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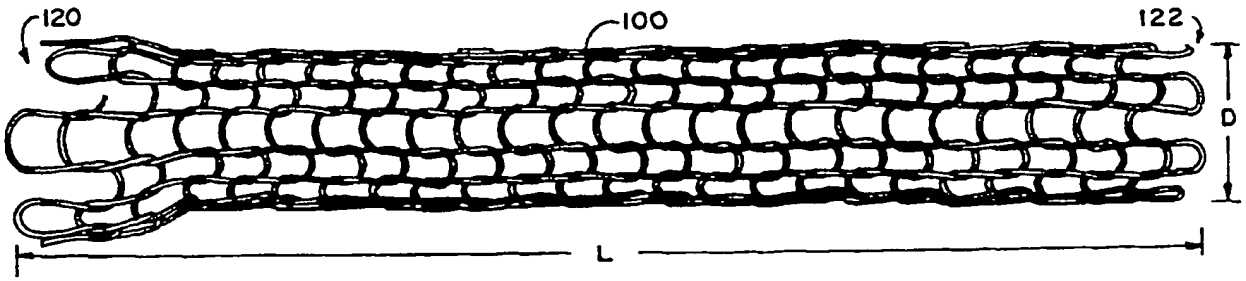

(57) Abstract

A stent (100) for reinforcement of the lumen of a peristaltic organ, and methods for forming, shaping and heat-treating of such a stent. The stent (100) is formed by knitting preferably a nitinol wire into a pattern of overlapping loops selected such that from a relaxed state each row of loops may shift axially relative to and independently of the rows on either side. A stent is also shown which comprises two resilient cylindrical mesh layers (532, 534) and a semi-permeable compliant membrane (530) such as expanded polytetrafluoroethylene, sandwiched between. A method is also shown of manufacturing a delivery system for a resilient tubular device such as a stent so that the device can be inserted into the body in a substantially reduced diameter.

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--STENTS FOR BODY LUMENS EXHIBITING PERISTALTIC--

Cross Reference To Related Applications

This application is a continuation-in-part of co-pending and commonly-owned application Serial No. 07/960,584, "MEDICAL STENTS FOR BODY LUMENS EXHIBITING PERISTALTIC MOTION" filed October 13, 1992, which is in turn a continuation-in-part of co-pending and commonly-owned application Serial No. 07/773,847, "Impregnated Stent" filed October 9, 1991, both of which are incorporated herein by reference. This application is also a continuation-in-part of application Serial No. 07/912,902, "Tubular Medical Prosthesis", filed July 13, 1992.

Field of the Invention

This invention relates to endoprosthetic stents that are placed within body lumens that exhibit physiologic motion such as peristaltic motion.

Background of the Invention

Medical stents are tubular endoprostheses placed within the body to perform a function such as maintaining open a body lumen, for example, a passageway occluded by a tumor. Typically, the stent is delivered inside the body by a catheter that supports the stent in a compacted form as it is transported to the desired site. Upon reaching the site, the stent is expanded so that it engages the walls of the lumen. The expansion mechanism may involve forcing the stent to expand radially outward, for example, by inflation of a balloon carried by the catheter, to inelastically deform the stent and fix it at a predetermined expanded position in contact with the lumen wall. The expansion balloon can then be deflated and the catheter removed.

In another technique, the stent is formed of a highly elastic material that will self-expand after being compacted. During introduction into the body, the stent is restrained in the compacted condition. When the stent has been delivered to the desired site for implantation, the restraint is removed, allowing the stent to self-expand by its own internal elastic restoring force.

Strictures of the esophagus often produce obstructive dysphagia resulting in debilitating malnutrition. To date, the theoretical advantages of placing a plastic stent to restore the patient's ability to swallow have been offset by technical difficulty of placement, morbidity and mortality associated with the procedure, and poor long-term prosthesis performance. In particular, previous stents have transmitted the force and deformation of peristaltic waves inappropriately, for instance causing the stent to creep toward the stomach, perforate the esophagus, or rupture the aorta.

Summary of the Invention

In a first aspect, the invention features a method for providing reinforcement to the lumen of a peristaltic organ. The stent is formed by knitting a filament into interknit loops, the pattern of the loops selected such that from a relaxed state each row of loops may shift axially relative to and independently of the rows on either side. The local lengthening and shortening allowed by the shifting allows the stent to accommodate the peristalsis of the organ without migrating within the organ.

Preferred embodiments of the stent feature the following. The lumen treated is the esophagus. The elongation factor ϵ by which the stent can locally lengthen by shifting is related to the angle θ at which the lumen can incline inward by the relationship: $\epsilon = 1.0 / \cos \theta$. The stent is knitted of metal wire to be self-

expandable such that the stent expands outward against the body lumen wall by an elastic restoring force of the wire. The stent is knitted from nitinol wire having a diameter of about 0.15 mm. The stent, in its free state, has a point of constricted cross-section. The constriction may have a valve.

A stent according to the invention offers the following advantages. The stent exerts a constant, gentle radial force on the wall of the lumen that maintains lumen patency and actively resists compression, as by a tumor. The inherent flexibility of the knitted stent adapts to peristalsis, transmitting the peristaltic wave to the lumen, but without changing overall length or creeping. This reduces complications and promotes long-term stability, patency, and patient comfort. The force exerted by the stent against the lumen is sufficient to compress the capillaries of the organ so that growth into the lumen is retarded. The stent can be delivered via a low-profile delivery system which is smaller than a standard endoscope. The small diameter of the delivery system simplifies implantation by eliminating the need for pre-dilating the stricture, and allows placement even in patients with tortuous esophageal anatomy or strictures prone to perforation by plastic stents.

In a second aspect, the invention features a stent for providing reinforcement to a selected region of a selected body lumen. The stent comprises two resilient cylindrical mesh layers and a semi-permeable compliant membrane sandwiched between.

Preferred embodiments of the invention feature the following. The two mesh layers may be knit of a flexible filament, and the knit may be configured so that the stent can adapt to peristalsis of the body lumen. The membrane is composed of expanded polytetrafluoroethylene.

The invention or preferred embodiments thereof may feature the following advantages. The semi-permeable

membrane prevents cell ingrowth of the stent. The force exerted by the stent against the lumen is sufficient to compress the capillaries of the organ so that growth into the lumen is retarded.

In a third aspect, the invention features a method of manufacturing a delivery system for a resilient tubular device so that the tubular device can be inserted into the body in a substantially reduced diameter. The method uses a confining block having a bore and a slot leading into the bore. The tubular device is pinched and inserted into the bore and the slot. Two mandrels are inserted into the bore, one inside the tubular device and one outside. The mandrels are revolved about each other to roll the tubular device on itself until the tubular device is entirely rolled and confined at the reduced diameter within the bore. The tubular device is removed from the bore while being restrained in the reduced diameter.

Preferred embodiments of the method of manufacture feature the following. The removing step may be accomplished by pushing the tubular device from the end of the bore and restraining the tubular device as it emerges. The restraining my be by means of wrapping a wire around the tubular device. The slot may be tangent to the bore of the confining block. The tubular device may be a stent knit of an elastic filament. One of the mandrels may be part of the delivery system that will be used to deliver the stent.

The inventive method of manufacturing the stent features the following advantages. Certain prior methods required several operators to simultaneously hold and constrain the resiliency of the stent and hurt the fingers of the operators. The method of the invention requires only one operator and is comfortable to execute. The stent delivery systems produced by the method are more uniform than those manufactured by previous methods,

both in distribution of stresses within a single stent and in variation between stents, thus avoiding deformation of the stent during manufacture and allowing the physician to place the stent more precisely in the patient. A stent delivery system manufactured according to the method has a small profile, and thus minimizes trauma to the patient during implantation.

In a fourth aspect, the invention features a method of manufacturing a wire medical device. The method includes the steps of: bending an elastic wire in a regular pattern so it defines, generally, the walls of a tube that has a substantially constant outer diameter and geometry and extends over a desired axial length; and shaping the tube to form a device having a different, desired diameter or geometry by applying a mechanically deforming force to the tube so it conforms to the diameter or geometry and, while maintaining the deforming force, heating and then cooling the tube such that the tube retains the desired diameter or geometry when the mechanical deforming force is removed.

Preferred embodiments of this method of manufacture may include the following features. The mechanical deforming force is exerted by confining the tube within a cavity of a die having a smaller diameter than the tube, and/or by stretching the tube over a mandrel having a larger diameter than the tube. The deformed shape may define a stent having one or both ends flared to a larger diameter than other portions of the stent. The deformed portion of the tube may extend over at least about 10% of its length.

In a fifth aspect, the invention features a method of manufacturing a wire medical device, including the steps: bending an elastic wire in a regular pattern to define the walls of a generally tubular medical device that has a desired outer diameter and geometry and extends over a desired axial length, the pattern including portions in

which the wire is in overlapping contact; and relieving stresses in the portions of overlapping contact by heating the tube for a proscribed period and then cooling the tube, the stresses in the portions of overlapping contact that were created during the bending being relieved to improve the capacity of the device to respond by internal motion when subject to the physiologic motions of a body lumen.

Preferred embodiments of this method of manufacture may feature the following. The tube is formed by knitting the wire. The knitting machine may have a knitting head formed from a durable, low-friction polymeric material, for instance delrin or nylon. Portions of the knitting needles in contact with the wire during knitting include a durable, low friction polymeric material. The wire is selected from the group consisting of a nickel-titanium alloy and molybdenum- or barium-containing highly elastic stainless steel. The tube is heated to about 400-500°C for about 20 to 30 minutes.

In a sixth aspect, the invention features a medical device for use in a body lumen. The medical device includes a tube formed by a flexible wire bent in a regular pattern to form the walls of the tube over a desired length, the pattern being configured to allow relative motion of adjacent portions of wire when the tube is subject to the physiologic motions of a body lumen. The tube has a shape of a varying outer diameter or geometry along its length, the shape being selected to improve the function of the device in the lumen in which the device is to be used.

Preferred embodiments of this sixth aspect may include the following features. The selected shape complements the inner wall of the lumen in which the device is to be used. The tube shape has a larger diameter for part of its length for contacting a portion of the lumen having a corresponding large diameter and a

smaller diameter for the rest of its length for contacting a portion of the lumen having a corresponding to smaller diameter. The tube shape has a flare to larger diameter at one or both ends and a smaller diameter portion adjacent the flared end(s), the smaller diameter portion selected to conform to the diameter of the lumen and the flare serving to anchor the device in the lumen. The flare extends to a diameter about 10-25% larger than the reduced diameter portion and has a length of about 15-25% of the length of the tube. The tube shape has a secondary flare formed by the wire at the end of the pattern. The bent regular pattern is formed by knitting.

In a seventh aspect, the invention features a valve device for implantation into a lumen of an organ of a body. The device is formed by a flexible wire bent in a regular pattern to form the walls of the tube over a desired length, the pattern being configured to allow relative motion of adjacent portions of wire when the tube is subject to the physiologic motions of the body lumen. A portion of the tube has a much reduced diameter, and is provided with a material that is substantially impermeable to body fluid. The device is capable of impeding the flow of body fluid through the reduced diameter portion until the pressure of the body fluid is sufficient to elastically widen the portion and allow flow therethrough, the portion of said device relaxing to its reduced diameter when the pressure of the bodily fluid decreases thereafter.

In preferred embodiments, this valve is configured as a valve for the urethra.

Other advantages and features of the invention will become apparent from the following description of a preferred embodiment, and from the claims.

Brief Description of the Drawings

Figs. 1 and 1c are perspective views of a stent according to the invention.

Fig. 1a is an end elevation view of the stent.

Figs. 1b, 1d-1h, 4a, 6, and 11g are detail views of the knitted loops of a knitted stent.

Figs. 2, 2a, 3, and 3a-3e are sectional views of a body, showing effects and operation of a stent in the esophagus.

Fig. 4 is a sectional view of a peristaltic organ.

Figs. 5, 5a, and 5b are schematic representations of alternate embodiments of the stent.

Fig. 5c is a partially broken-away view of an alternate embodiment.

Figs. 6a, 7, 7a, 7c-7j, 7l, 7m, 7p-7s, 10a-10c, 11, and 11a-11f are perspective views of tools and a time sequence of steps in processes for manufacturing a delivery system for the stent.

Fig. 6b is a perspective view of an alternate embodiment.

Figs. 7b, 7k, 7n, and 7o are cross-sectional views taken during the process of manufacturing the delivery system.

Fig. 7t is a sectional view of the delivery system.

Fig. 7u is a perspective view of the delivery system, cut away.

Figs. 8 and 8a-8e are a time sequence of sectional views of an esophagus showing delivery of a stent.

Figs. 9, 9a, and 9b are a time sequence of cutaway views of an alternate delivery method.

Fig. 10 is a perspective view, partially cut-away, of a die and a stent being formed in the die.

Description of Preferred Embodiments

Referring to Figs. 1 and 1a, a stent 100 according to a preferred embodiment is formed of a knit cylinder with length *L* and diameter *D*. The knitting forms a series of

loosely-interlocked knitted loops (e.g., as indicated by adjacent loops 132 and 134 in Fig. 1b) that may slide with respect to each other. This sliding or shifting allows the stent to adapt to the movement of the organ without moving axially in the organ. The adaptation is accomplished with mere bending of the stent filament.

The stent maintains its axial working length L when locally radially compressed, by locally lengthening or shortening due to shifting of the rows of loops relative to each other. Fig. 1c shows a region 130 of the stent not under radial compression where adjacent loops 132 and 134 are in an overlapping, relaxed configuration, and the heads of the loops are separated by a short distance s. In the case of an esophagus, a large piece of food distends the esophagus. At the first instant of the expansion, the wall may be deflected by an angle θ, but the diameter of the organ will not have changed appreciably. In such a region, 140 in Fig. 1c, the local length of the wall elongates by a factor $1/\cos\theta$. The rows of loops of the stent shift axially with elastic deformation of the wire of the loops so that the separation of the heads increases to a loop length l_1, as shown in Fig. 1e. In the region of maximum expansion 150, the length of each portion of the esophagus returns to its rest length, but the diameter is extended. The knit loops of the stent can widen, as shown in Fig. 1f, to accommodate this extension. Returning again to considering any peristaltic organ, the organ contracts (c of Fig. 1c) to compress a region. In a region 160 where the wall is at an angle of deflection θ but the diameter is essentially equal to the rest diameter, the length of the wall of the organ will elongate by a factor $1/\cos\theta$, and the loops will again pass through a state where their width is essentially the same as the rest width, but, by relative shifting of the rows of loops axially, they are extended to length l_1, the state shown in Fig. 1e. In a

region of maximum compression 170, the wall of the organ is at its rest length, but the circumference is much reduced. In this region, the loops of the stent deform into the configuration of Fig. 1g, where the length of the loops is s but the width is compressed. Finally, as the peristalsis relaxes, the wall of the organ returns to its rest length and rest circumference, region 190 of Fig. 1c, and the loops of the stent return to the overlapped rest configuration of Fig. 1d.

In the case of organs that can constrict almost closed, as the lumen compresses radially the circumference shortens, and thus part of the length of the filament that contributes to the circumference of the stent in its rest state is freed to contribute to length, and thus the loops can lengthen to length l_2, as shown in Fig. 1h.

The lengthening from s to l_2 all occurs without significant elongation of the filament of the stent itself, only by elastic bending deformation and sliding of the rows of loops against one other. The ratio of the maximum local length to the relaxed local length, l_2/s, is determined by the configuration of the loops and the elastic limit of the material of the filament.

Referring again to Fig. 1c, the local lengthening in regions of radial extension, compression or slope does not substantially affect the loops in nearby regions that are not exposed to the radial compression, which are in turn free to elongate, contract or widen in response to the movements of their own local portions of the organ. Thus, the stent maintains its overall working length L even when locally extended or compressed. When the radial compression is released, the elasticity of the filament causes the stent to expand back to its original rest diameter D without change of the overall length, since adjacent loops in the region of compression slide back to the relaxed overlapped state, separated by

distance *s*. Because the stent maintains point-for-point contact with the organ, averaged over a local area about the size of one loop, the stent maintains its placement in the organ, and does not migrate with the peristalsis.

A further property of the stent is that the state characterized by all adjacent loops being separated by distance *s* is the stable equilibrium between the elastic restoring forces of the wire and the compressive force of the esophagus. Thus, the stent automatically adjusts to overall length *L* regardless of the initial configuration of the loops and length of the stent. For example, if the loops are in extended positions as in Fig. 1e or 1h, then upon compression the loops adjacent the compressed region draw axially inward to the relaxed configuration in Fig. 1b, thus drawing the proximal end (120 of Fig. 1) and distal end 122 inward. When the compression releases, the loops in the region of the compression also shorten, since the ends 120 and 122 of the stent have been drawn inward and adjacent loops slide inward to adjust for the reduced overall length. Once the stent has settled into this equilibrium state, the overall length and position within the lumen are stable.

These features are enabled in the preferred stents of the invention by a sliding motion of adjacent filament loops, which in turn is enabled by the method of knitting that reduces overlap of the loops, as shown, and the elasticity of the filament and the shape of the loops. The sliding motion allows local axial lengthening or shortening of the stent substantially independently of other remotely located portions of the stent. The elasticity of the stent filament allows the stent and lumen to return to their desired patency when the compacting force is removed, without inelastic deformation. The loops are configured so that the stent assumes its desired diameter and overall length as the elastic restoring forces seek their minimum stress, the

relaxed state of Fig. 1b. This minimization occurs when adjacent loops touch at their widest points, as for instance point 136 between loops 132 and 134.

These features are particularly useful in body passages in which physiologic function includes motion of the lumen walls, such as peristaltic motion of the esophagus. For example, referring to Fig. 2, an esophagus 200 is occluded by a tumor 202. In Fig. 2a, after insertion of the stent 100, the lumen's patency is restored. Once implanted in the esophagus, the stent is held in a rest diameter that is slightly compressed by the esophagus from its free diameter when outside the body. It is the elastic restoring force of the stent resisting this compression that holds the stent in place.

A stent for an organ like the esophagus, according to the invention, not only holds the lumen open but allows the organ to maintain its physiologic motion. Further, the stent adapts to this motion without itself being subject to the peristaltic force -- it does not creep toward the stomach with each esophageal contraction, nor does the overall length change. The operation of the elastic knitted stent is illustrated in Figs. 3 and 3a-3e. A food particle 310 is urged through the lumen 320 by a peristaltic wave 322 that propagates down the esophagus 200. The wave is induced by circumferential contraction of the muscular tissue surrounding the lumen, a consequence of which is radial inward extension of the wall. Before the wave reaches the stented portion, the stent lies between points *T* and *B*, with length *L* between. As the wave reaches point *T* and the portion of the esophagus reinforced by the stent 100, the stent complies with the radial contraction, as shown in Figs. 3a-3e. As shown in Fig. 3e, after passage of the peristaltic wave the stent has not migrated from points *T* and *B*, and maintains its overall length *L*. The adjustment and restoration feature allows the stent to maintain its

position in the lumen, without migrating axially as might occur with a unitary structure in which stresses in one portion are substantially transmitted to other portions.

Referring to Figs. 4 and 4a, the configuration of the knit loops of the stent may be determined based on the degree of radial motion and consequent axial lengthening imposed by the peristaltic motion. Generally, the loop length of the stent in its extended position l can be expressed as:

$$l = \epsilon s \qquad (1)$$

where s is the axial length of the portion of the body lumen over which two adjacent loops of the stent extend, and ϵ is the factor by which the stent must elongate in response to local lengthening of the body lumen wall. It will be seen that the maximum local lengthening will occur over the portion of the wall that lies at the largest angle θ from the at-rest position. In a worst-case limit, the entire peristaltic wave can be approximated as having a wall at angle θ, thus distending a portion of the lumen that has rest length a to a triangular wave with hypotenuse b. Thus,

$$b/a = 1/\cos\theta \qquad (2)$$

This ratio, b/a, is the elongation factor by which the loops must lengthen from their relaxed length s to their extended length l to accommodate the lengthening of the lumen wall at the incline of the peristaltic wave. Thus,

$$b/a = 1/\cos\theta = l/s = \epsilon \qquad (3)$$

For the stent as a whole to maintain point-for-point contact with the wall of the lumen and thus for the stent as a whole to remain stationary along the axis of the lumen, the heads of the loops are allowed to slide locally in the region of peristaltic compression by a distance $(l-s)/2$.

It will be noted that the stent will accommodate the elongation of the lumen wall if it is capable of local elongation ϵ equal to $1/\cos\theta$, independent of the amount

of deflection *c*, even in the extreme case where the organ is capable of constricting completely shut -- deflection *c* in Fig. 4a being equal to the radius *D*/2 of the lumen.

The amount of force exerted by the stent against the lumen wall is chosen to exceed the blood pressure within the capillaries of a typical tumor, and thereby prevent the tumor from further growth into the lumen of the esophagus. The exerted force is determined by the coefficient of elasticity of the filament, by the configuration of the loops and density of the knit (loops per unit of axial length), and by the diameters of the lumen and the stent. For instance, a stent design would exert more force against the lumen wall by choosing a stiffer material for the filament, by knitting the stent with more, smaller loops per unit of length (decreasing *s*, and reconfiguring the loops to maintain the ratio *l*/*s*), or by knitting the stent to a larger rest diameter *D*. The radial force exerted is bounded at the point where the loops reach the relaxed configuration of Fig. 1b and the stent's diameter reaches diameter *D* -- the forces sum to zero at the contact points 136, and the force exerted on the lumen itself falls to zero. Thus, the diameter *D* of the stent must be slightly larger than the diameter of the lumen if the stent is to retain its place in the lumen.

Referring again to Figs. 1, 1a and 1b, a particular embodiment for use as an esophageal stent is knitted of nitinol wire of about 0.15 millimeters in diameter to have a diameter *D* of about 18mm, though diameters of 14mm to 25mm may be useful. The proximal end 120 is flared to 20mm, to secure fixation to the esophageal wall. Stents manufactured in overall lengths varying from 5 to 15cm allow selection of a stent tailored to the patient's needs. The relaxed loop length *s* is about 0.80-0.85mm, and the maximum loop length *l* attained without significantly distorting the loops is about 1.05-1.15 mm.

This elongation factor of about 1.4 is close to $\sqrt{2}$, allowing for a maximum angle θ of about 45°. The peak-to-peak height p of the loops is about 2.2mm when the loops are in their rest state.

Examples of filament materials include shape memory metals, for example, nitinol, tantalum steel, stainless steel or other elastic metals, or plastics such as polyester, polypropylene, or carbon fiber. The filament may be selected to have a sufficiently high elastic limit to allow the delivery system to rely entirely on this elasticity, rather than, for example, the balloon 820 of Fig. 8e to expand the stent. The filament may be formed of a two-component metal wire system that exhibits desirable physical properties such as enhanced radiopacity along with desirable mechanical properties, such as extreme elasticity. A full discussion of composite medical wires will be found in U.S. application serial number 07/861,253, "Medical Wire" by Kevin R. Heath, incorporated herein by reference. The stent may be knit of two or more filaments.

As shown in Fig. 4a, the stent is knitted of a single filament. This view shows only the front half of the stent. The loops that appear in this view as independent rows in fact are a single spiral-wrapped sequence, much as a common screw has only one ridge from head to tip. In alternate embodiments of the stent, multiple filaments or other knits could be used, so long as the knit structure allows a single row to elongate without forcing the two adjacent rows to shift. The last loop of the wire is cut 440. To prevent the stent from unravelling, the last three loops (two shown, 450 and 452) of the stent are coated in urethane, as shown in Fig. 4b. The coating also covers the sharp ends of the filament.

It will be realized that the stent is applicable to malignant or benign obstructions of many other organs. Stents to treat biliary duct obstructions, for instance

when treating liver sclerosis or bleeding, would be about 8 to 10mm in diameter and 4 to 8cm in length. Stents for the ureter would be about 6 to 10mm in diameter and about 2 to 10cm in length. Urethral stents would be about 10 to 20mm in diameter and about 2 to 6 cm in length. Stents for the prostatic urethra would be about 10 to 20mm in diameter and about 2 to 6cm in length. Colonic stents would be about 10 to 20mm in diameter and about 4 to 10 cm in length. Stents for hemodialysis shunts would be about 6 to 8mm in diameter and about 2 to 6cm in length. Stents for the porta canal would be about 8 to 14mm in diameter and 4 to 8 cm in length. Stents for the trachea and bronchi would be about 8mm to 25mm in diameter and 1 to 8 cm in length. Stents for gastric outlet obstructions would be about 8 to 20mm in diameter and 1 to 25 cm in length. Peristaltic stents may also be configured for aortic aneurysms or dissections (preferably weaving the filament material with a covering such as dacron), and treatment of superior vena cava syndrome and venous restrictions. The invention is also useful in lumens in which compression is caused by some outside force, for example in blood vessels compressed by muscular contraction, movement of an extremity, or pressure exerted by an object external to the body.

Figs. 5, 5a, and 5b represent alternate forms for stents. (Showing the knit loops in these projections would obscure the shape; these figures represent only shapes of the stents.) The stent could be shaped to include, in its free and rest states, a narrowing at a point in its length. This narrowing would accommodate the stent to the anatomy of a natural sphincteric structure, for instance the pylorus or the cardia. A stent so narrowed would enable the organ to close, for instance to prevent reflux. The narrowing could be shaped at one of the ends, for instance for use in the

rectum at the anus or in the common duct for a Papilla of Vater.

The narrowing could be shaped conically, as in Fig. 5 for use in sphincter organs. Fig. 5a shows a stent incorporating a flattening, with the circumference in the area of the flattening reduced so that the width remains constant. The latter embodiment could be used in an occlusion with two lips such as the vocal cords. In either case, it may be desirable to form the loops in the region of the constriction so that their free state is similar to one of the compressed configurations, e.g. Fig. 1g, so that the constriction is capable of opening to the rest diameter *D*.

As shown in Fig. 5b, the margins of the narrowing could incorporate a valve to ensure complete closure of the stented organ, as for instance the reinforced lips 520. This valve could be opened and closed either by the muscles normally surrounding the point of constriction, or by a manually-operated control extended to outside the body. This would allow the use of the stent, for instance, across the aortic valve or as a replacement for the urinary sphincter. It may be desirable to reinforce the point of the constriction, e.g., with a stiff wire, especially in conjunction with the flattened constriction of Fig. 5a. It may also be desirable to provide a valved stent with a watertight membrane, similar in form to that discussed below and shown in Fig. 5c.

The stent can be made to exert varying force along its length, for instance by varying the gauge of the wire or the density of the knit. In the narrowed stents discussed above, it may be desirable to make the stent particularly flexible in the region of the narrowing.

Some tumors are so invasive that the stent is quickly ingrown by the tumor. As shown in Fig. 5c, the stent may be manufactured with an elastic semi-permeable membrane 530 of porosity less than 50 microns and of very low

modulus of elasticity, sandwiched between two knit layers. The membrane may advantageously be of expanded polytetrafluoroethylene (teflon) or latex. The inner layer 532 is essentially identical to the single-layer stent, providing most of the elastic force against the lumen. The outer knit layer 534, which acts to retain the membrane, is typically constructed of thinner wire, for instance 0.07mm diameter, or a less-resilient material such as polypropylene or polyethylene. The outer knit layer is slightly shorter in length than the inner layer.

The stent is knit on a conventional knitting machine, very similar to that used to knit stockings. During the knitting process, the wire is deformed past its elastic limit. Referring to Fig. 6, on some knitting machines, or for stents of some diameters, it may be convenient to produce a knit with the "up loops" 610 of a different shape than the "down loops" 612. In some applications, for instance the aorta, it is important that the loops be uniform so that the stent exerts uniform pressure along the lumen wall. During the knitting process, the wire will be under tension, and thus the loops will be in a tight configuration, similar to Fig. 1e, or possibly to Fig. 1f or 1h depending on the geometry and setup parameters of the knitting machine itself.

The knitting machine produces a long "rope" of knit loops. The rope is cut into lengths somewhat longer than the final length of the stent. The extra length allows for the shortening of the stent that will occur as the loops are shortened from the elongated state in which they emerge from the knitting machine to the rest state of Fig. 1b, and allows for some trimming. As shown in Fig. 6a, after knitting, the stent is mounted on a mandrel 620 for annealing, to relieve the strains induced by the plastic deformation of knitting and to produce greater elasticity in the wire. The mandrel is in the

free shape of the stent, 18mm in diameter with a flare 622 to 20mm at one end.

To achieve the constricted embodiments of Figs. 5 and 5a, the mandrel would have a constriction formed in it, and an external restraint would be applied to the stent so that the annealed shape would be as shown in those figures. As the stent is loaded onto the mandrel, the operator shortens the overall length so that the loops assume the relaxed, shortened state of Fig. 1b. The stent is annealed at approximately 450°C for about 15 minutes.

After annealing, the stent is cut to its final length, and the three loops at each end of the stent each receive a drop of urethane (450 of Fig. 4a or Fig. 6) to prevent unravelling.

Alternately, the stent may be knit of interlocking pre-formed sinusoidal rings, two of which 630, 632 are shown in Fig. 6b.

The stent itself is packaged into a delivery catheter as shown in Figs. 7 and 7a-7u. The center of the delivery catheter is a carrier tube 700, shown in Fig. 7. The carrier is a flexible tube of Pebax, a polyether/polyamide-12 resin from Atochimie with desirable flexibility/rigidity characteristics, 2.5mm in diameter and approximately 80cm long. The carrier has several radiopaque O-rings 704,706 mounted along the most-distal 20cm. The preferred radiopaque material is tantalum.

The preferred process of mounting the stent on the carrier tube 700 uses several tools: a confining block, two mandrels, and a pusher. The confining block 710, shown in Figs. 7a-c, is cylindrical, somewhat longer than the stent itself at about 20cm, and formed of a rigid plastic with low friction characteristics, preferably delrin or nylon. The block has a drilled bore 712 of 8mm diameter, with a 1mm-wide slot 714 cut from the top of

the outside of the block and meeting the inner bore 712 at a tangent. The slot and bore may have a guideway 718 formed, to make the following steps easier. The block may also have flats 716 milled in the bottom so that the block may be mounted in a vise. A first mandrel 720, shown in Fig. 7d, is a simple rod approximately 30cm long and about 3mm in diameter. A second mandrel 722, shown in Fig. 7e, has a shaft of about 3mm diameter and length longer than the confining block, two handles 724, each about 10mm in diameter, with center bores that friction fit on the ends of the mandrel shaft, and slots 726 of width to accommodate the carrier tube. Both mandrels have rounded ends so that they will not catch on the loops of the stent. A third tool is a pusher 728, shown in Fig. 7f, with a shaft 729 of slightly less than 8mm diameter and a bore 730 somewhat larger than the outer diameter of the carrier 700. The bore may either be the full length of the pusher, or as shown in Fig. 7f, may have a breech hole 732. A fourth tool, which will be seen in Fig. 7q, is a soft copper wire with a silicone sheath 760 (silastic) over it. The sheathed wire is about 50cm long, and the sheath is about 1-2mm in diameter.

Referring to Fig. 7g, the confining block 710 is securely mounted, as in a vise 750. An operator squeezes a stent 100 flat and works it into the slot 714 preferably starting at a corner 752, and bottoms it in the bore 712. Referring to Fig. 7h, the stent is positioned in the confining block so that the proximal end 120 of the stent extends from the end of the confining block. The first mandrel 720 is inserted into the distal end of the carrier 700, and then the mandrel and carrier tube are passed through the center of the stent. The operator slides the stent to the center of the confining block, as shown in Fig. 7i. Referring to Fig. 7j, the stent is slid back so that the flared

proximal end again extends from the end of the confining block. One handle of the second mandrel is removed, and the shaft 722 of the second mandrel inserted through the bore of the confining block but outside the stent. Referring to Fig. 7k, the first mandrel 720 lies inside the carrier tube 700, which in turn lies inside the stent 100. The lower portion of the stent and the second mandrel 722 lie inside the bore 712 of the confining block. Referring to Fig. 7l, the stent is slid back to the center of the confining block. The several slides forward and back equalize the distribution of the knit loops evenly over the length of the stent. The second handle of the second mandrel is affixed to the shaft of the second mandrel, and the slots 726 of the handles engaged with the carrier tube 700 and/or first mandrel 720. The operator can center the O-rings 704,706 within the stent so that the carrier will be axially positioned roughly correctly within the stent. Referring to Fig. 7m, the operator twists the handles, revolving the two mandrels about each other and winding the stent about the two mandrels. Fig. 7n shows the configuration of the stent and the two mandrels after about half a revolution. The operator continues winding until the stent is completely rolled on itself in the bore of the confining block. The operator removes a handle from the second mandrel and removes the second mandrel from the confining block. The stent is held in the wound conformation by the confining block, as shown in Fig. 7o.

Referring to Fig. 7p, the operator threads the pusher 728 over the proximal end of the carrier, with the shaft 729 distal. The pusher will be used to slowly push the stent out of the bore of the confining block.

Referring to Fig. 7q, using the pusher the stent is pushed out of the confining block by about 1cm. The operator makes any final adjustments required to center the radiopaque O-rings within the stent. The operator

wraps several turns of the copper wire and silicone sheath 760 around the exposed distal end 122 of the stent, with about a 1mm gap between turns, and lays the bight of the sheathed wire into the slot of the confining block. Referring to Fig. 7r, the operator gradually feeds the stent out of the confining block using the pusher, and wraps the sheathed wire around the stent to keep it confined to a diameter of about 8mm. The operator maintains a roughly uniform 1mm spacing between wraps.

After the stent is fully bound in the copper wire 760, the pusher is removed back over the proximal end of the carrier tube and the carrier tube is pulled out of the bore of the confining block, the stent and silastic/copper wrap is dipped in U.S.P. grade dissolving gelatin, and the gelatin is allowed to set. The copper wire can then be unwrapped; the silicone sheath acts as a release surface so that the gelatin peels off the wire and remains set on the stent in a 1mm-wide "threaded" strip, 770 in Fig. 7s, confining the stent.

Referring to Figs. 7t and 7u, the stent delivery system catheter 799 is completed by affixing a nose piece 772 onto the distal end of the carrier 700, and surrounding the entire assembly in a cylindrical sheath 774. Both the carrier and sheath are essentially rigid in the axial direction, so that they can be used to push or pull the catheter to position it, and so that handles 782 and 784 can be squeezed together to retract the sheath from over the stent. Also shown in Fig. 7t are the radiopaque markers 704,706 and in Fig. 7u graduation markings 778 on the sheath, both of which will be used during implantation to guide positioning. The inner pair of the markers indicate the length the stent will assume at its 18mm fully-expanded diameter, and the outer pair indicate the length of the stent when compressed to 8mm

diameter. A guidewire 778 will be threaded through the center bore 776 of the carrier during implantation.

The process of implanting the stent is illustrated in Figs. 8 and 8a-8e. Referring to Fig. 8, using an endoscope 810, the proximal margin 812 of a stricture 814 is identified. The guidewire 778 is advanced across and beyond the stricture. In Fig. 8a, an 8cm-long balloon 820 is advanced over the guidewire and inflated to 12mm diameter, dilating the stricture to 12mm. After examining the stricture endoscopically and fluoroscopically, a gelatin-encased stent 4-6cm longer than the stricture is chosen. The delivery system 799 is passed over the guidewire and advanced until the distal inner radiopaque marker 704 is 2-3cm below the distal margin 832 of the stricture.

Referring to Fig. 8c, The outer sheath is retracted by squeezing together handles 782 and 784 (see Fig. 7u), and the stent begins to deploy. The gelatin will immediately begin to dissolve, allowing the stent to expand under its own elastic restoring force. The material of the stent filament, nitinol, is chosen so that even the fairly severe deformation required to compact the stent into the delivery system does not exceed the elastic limit. Referring to Fig. 8d, after the proximal 120 and distal ends 122 of the stent have expanded and firmly attached to the esophageal wall, the catheter 799 can be removed. Referring to Fig. 8e, depending on the patient, a 12mm-diameter balloon 820 may be inflated within the stent to ensure that the occlusion is opened to the desired patency, to affix the stent firmly to the esophageal wall, and to ensure adequate esophageal lumen size for endoscopic examination. Peristaltic contractions of the esophagus will allow the stent to "settle" into its most-relaxed configuration.

Referring to Fig. 9, in another delivery system, the stent 100 is formed of an elastic filament material that

is selected so compaction produces internal restoring forces that allow the stent to return to its rest diameter after the compacting restraint is removed. The stent may be compressed onto a catheter 900 that includes a sleeve 902; the sleeve holds the stent in a relatively compacted state. The compaction is typically achieved by rolling the stent upon itself using two mandrels, as in Figs. 7g-7o. In other cases, the stent may be positioned coaxially over the catheter. The catheter is positioned within the lumen at the region of the tumor 202. In Fig. 9a, the sleeve is removed from about the stent, for example, by withdrawing axially in the direction of arrow 910, thus allowing the stent 100 to radially expand by release of its internal restoring force. As shown in Fig. 9b, the axial force exerted by the stent is sufficient to dilate the lumen 200 by pushing the tumor growth 202 outward, or in some cases to compress the occlusion against the lumen wall. The catheter can then be removed.

An aspect of the invention is to form stents that have a shape or profile along their length that is adapted for a particular application in a particular body lumen. The profile is effected by knitting a stent of constant diameter and geometry, mechanically deforming the stent into a desired shape with a different diameter or geometry, and then heat treating the stent so it maintains that shape after the mechanical deforming force is removed. The deforming force, applied prior to heat treatment, is usually less than that required to plastically deform the stent wire. However, plastic deformation prior to heat treatment may also be used in some cases.

The shape of the stent can be selected to have a variable diameter such as a flare at one end that helps anchor the stent in a lumen that has inherent physiologic lumen wall movement such as peristalsis. The transition

between the larger diameter flare and smaller diameter portion can be a gradual taper. In an esophageal stent, the flare is usually positioned upstream of the smaller diameter portion. The larger diameter of the flare and the taper provide a smooth transition to the smaller diameter portion, which reduces the likelihood that food particles will be caught on the stent. The flare is preferably of a considerable length extending over multiple knit-loop rows. The flare may be, e.g. about 5-25% of the overall length of the stent, and also of considerable width, extending for example, to diameters 5-35% larger than the diameter of the main body of the stent. The flare may be of a non-uniform diameter, for instance, similar to a trumpet bell.

The stent can also be shaped to complement the varying diameter of a body lumen. For example, a stent for the bronchial tract includes a portion of e.g., 15mm diameter, that is positioned in the trachea, and a smaller diameter portion, e.g. 11mm, that extends into a bronchus (side branch). The stent has a tapered transition region about 1 cm long between the two portions. For use in the colon, the stent can have a flare at both ends, to affix the stent to the lumen wall at both ends. Other important lumens include the biliary duct, the prostatic urethra, and the vascular system, where the axial stretching motion of, e.g., the wall of a coronary artery or aorta, is accommodated by the movement of the knit loops in a manner similar to the discussion above with respect to radial narrowing in peristalsis.

Referring to Fig. 10, a shaped stent may be formed by applying a confining force to a uniform stent at desired locations along its length using a die 1000. Die 1000 is formed of heat resistant material, such as a piece of 1mm-thick 360 stainless steel tubing. Die 1000 includes a portion 1002 of inner diameter essentially equal to the desired rest outer diameter *D* of stent 100, with enlarged

portion 1004 of inner diameter equal to the outer diameter of the desired flare. The die has a portion 1003 that has a gradual transition between the larger and smaller diameter portions. The non-flared end 1006 of the stent is extended beyond the die, wrapped around the outside of the die, and held in place with a retaining wire 1008. The assembly is heat treated. After heat treatment, the wrapped end 1006 is cut off so the stent can be removed from the die. After it is removed, the stent retains the shape of the die. (Alternately, the die may have a constricted portion 1002 of cross section equal to the desired cross section of a desired constriction, as shown in Figs. 5 and 5a.)

An advantage of using a die to confine the stent is that the end loops of the stent can be formed having the same diameter as the adjacent loops of the body of the stent. Typically, after heat treatment over a mandrel, the end loops 1070 of the knit extend outwardly because of residual stress, forming a short end loop flare, as shown in Fig. 10c. This short end loop flare is an advantage in many cases, such as for esophageal stents, to help anchor the stent and prevent food particles from collecting on the end loops. The short end loop flare is most useful as a secondary flare on the upstream end of the stent, at the end of the main anchoring flare. In other applications this flare may not be needed or could damage tissue in the lumen wall. The secondary flare is also particularly useful with delivery systems that attach to loops of the stent, for instance that disclosed in U.S. Application Serial No. 08/065,238, filed May 20, 1993, incorporated herein by reference.

Referring to Fig. 10a, in another embodiment, one end the stent 101 is confined within a die 1010 and the other end is stretched over a mandrel 1012. After heat treatment, the maintains a shape having one large diameter end, larger than the original knit diameter, and

one small end, smaller than the original knit diameter, with a transition region in between.

Referring to Fig. 10b, in another embodiment, both ends of a stent are stretched over separate mandrels 1014, 1015. After heat treatment, the mandrels are removed from the ends and the stent maintains flares of enlarged diameter at either end with a midsection having a diameter that corresponds to the original knit diameter.

Stents having various shapes can be constructed using these techniques. The cross-sectional geometry of the stent can be varied by varying the geometry of the die or mandrel. The shaping technique can be used to form medical devices other than stents. For example, in a particular embodiment, the knit tube is formed into a vascular valve, e.g. for the heart, by shaping the stent to have a large diameter approximating a lumen diameter at one end and a neck-down to very small diameter at the other end. After shaping, the knit-form is covered with a blood impermeable polymer such as silicon or urethane. The device is implanted in a blood vessel with the large diameter end anchoring the device to a blood vessel and the small diameter end oriented downstream. The small diameter end substantially obstructs the flow of blood until sufficient blood pressure builds to force it open, allowing a large flow of blood to pass until the pressure again subsides and the end of the device again relaxes to its small diameter state. The polymer thickness and elasticity may, but need not, be selected to enhance the opening and closing of the small end of the device. In another embodiment, a valve of this construction can be implanted in the prostate to treat incontinence. The valve prevents urine from passing until sufficient pressure builds. The valve may be constructed so that it can be opened by the patient relaxing the muscles in the urinary tract that prevent urine flow.

Another important feature of the invention is to heat treat the knit medical devices to reduce the stress caused by the knitting process and therefore make the device, e.g. a stent, more compliant and longer lasting. As illustrated in Figs. 1d-1h, adjacent rows of knit loops have portions that overlap and are in contact. During the knitting process that forms this structure, the metal filament is bent, which introduces stress that can create in the stent a certain stiffness. At the portions of overlap this stiffness can cause one row of knit loops to hinder the motion of the adjacent row and therefore reduce the compliance of the stent and reduce its ability to conform to the physiological motion of the lumen wall in which it was placed. Moreover, the stiffness also can cause increased abrasion at the overlap regions, which can reduce the stent lifetime. These concerns can be alleviated by proper heat treatment to reduce the stress created in the overlap regions by the knitting and increases elasticity. The stress can also be alleviated by coordinated selection of the diameter of the knitting wire and the amount of curvature of the knit loops. Generally, the smaller the knitting wire and the larger the loop size, the less stiffening-type stress in the resulting knitted device. The heat treatment may as well vary with these parameters.

The heat treating not only reduces the stresses in the overlap regions but recovers the tensile strength of the stent wire. The heat treating conditions are dependent on the degree of work hardening incurred during knitting which weakens the wire. The more bending, the greater the work hardening. For example, for a wire having a tensile strength of 250,000 - 300,000 psi may have a tensile strength of 70-90,000 psi, after knitting into an esophageal stent. After heat treating, the tensile strength is recovered, for example, to 180-190,000 psi. The heat treatment to reduce the stress in overlap regions and recover tensile strength can be

effected simultaneously with the heat treatment to shape the stent. The heat treatment to reduce the stress in the overlap regions and recover tensile strength is useful even when the stent is not shaped.

The performance of the knitted medical device can be improved by manufacture on a knitting machine constructed to limit abrasion of the knitting wire during knitting. Referring to Fig. 11, a knitted stent may be manufactured on a conventional circular knitting machine 1100, very similar to that used to knit stockings. The knitting machine includes a knitting head 1102 for guiding a series of needles 1104 which are axially extended and retracted by a rotating (arrow 1106) contoured platen 1108.

The portions of the machine that contact the knitting wire are constructed of a low friction durable polymer to reduce abrasion. The knitting head 1102, conventionally of iron or steel, is preferably constructed for medical device applications from a low friction durable member such as nylon or delrin (polyacetate) which reduces abrasion, scratching and nicking of the stent wire as it is drawn into the knitting head, as discussed in more detail below. The needle heads 1120 may also be formed of or coated with such a polymer.

The wire 1110 feeds from a spool 1112 to the needles during the knitting operation. The knit stent 100 is produced around a polymeric mandrel 1114 which is drawn downward in the direction of arrow 1116. Referring particularly to Figs. 11a-11d, each needle 1104 includes a needle head 1120 and a pivoted needle tongue 1122. During the upstroke of the needle (Fig. 11a), the head 1120 grasps the wire 1110, the tongue 1122 being initially in the downward position. On the downstroke (Fig. 11b), the tongue 1122 is deflected upward as it engages the portion of the knitting head 1102, thus enclosing the strand within the head. The downstroke (Fig. 11c) continues for a selected length within the

knitting head, deforming wire 1110 past its elastic limit, forming a loop 610 in the wire. On the upstroke (Fig. 11d), the strand deflects the tongue 1122 downward, thus releasing the strand from the needle head 1120. Because the stent 100 is being pulled down (arrow 1116), loop 610 is pulled (arrow 1116) so that it ends up pointing up. The cycle is repeated as the platen 1108 rotates. As shown in Fig. 11e, on some knitting machines, or for stents of some diameters, it may be convenient to produce a knit with the "up loops" 610 of a different shape than the "down loops" 612. In some applications, for instance the aorta, it is important that the loops be uniform so that the stent exerts uniform pressure along the lumen wall. During the knitting process, the wire will be under tension, and thus the loops will be in a tight configuration, similar to Fig. 1e, or possibly to Fig. 1f or 1h depending on the geometry and setup parameters of the knitting machine itself.

Referring to Figs. 11e and 11f, many of the geometric parameters of the knit stent are determined by the configuration of the knitting head 1102. Knitting head 1102 is generally a frustum of a cone, with a central throughbore and a plurality of slots 1160 down the side. The number of loops 610 around the circumference of the stent is determined by the number of needles 1104 that travel in slots 1160 of the knitting head. The overall diameter *D* of the stent is nearly equal to the diameter 1162 of the throughbore of the knitting head. The width 1154 of the up loops 610 is related to the diameter of needles 1104 and the width of knitting head slots 1160: a smaller needle in a narrower slot forms a narrower loop since the strand bends more acutely around the narrower needle head. The width 1156 of down loops 612 is related to the width 1164 of the lands between knitting head slots 1160. The amount of compressibility of the stent, for instance to compress the stent from its working rest

diameter to the diameter required for packaging into a compact delivery system, is most strongly influenced by dimension 1156, the width of the down loops 612. For instance, a stent can be made more compressible while retaining its diameter by reducing the number of loops in its circumference but widening dimension 1156. As shown in Fig. 11g, when such a stent is compressed, the down loops 612 bow and the shoulders of the loops can be forced to overlap, as shown in region 1170.

The knitting machine produces a long "rope" of knit loops. The rope is cut into lengths somewhat longer than the final length of the stent. The extra length allows for the shortening of the stent that will occur as the loops are shortened from the elongated state in which they emerge from the knitting machine to the rest state of Fig. 1b, and allows for some trimming. The knitted tube, of constant diameter is then stress relieved and shaped as discussed above.

Accordingly, using the methods and teaching above, in preferred embodiments, the wire may be 0.002" to 0.010" in diameter, obtained from, for example, Shape Memory Applications of Sunnyvale, CA, which was drawn by Fort Wayne Metals from, for example, 1/4", nickel-titanium alloy wire with an A_f equal to -5 to +10°C, available from Furukawa Electric Company of Japan. After drawing, the wire has a tensile strength of about 250,000 psi to 300,000 psi. The knitted tube for an esophageal stent is heat treated at 400°C in vacuum for 20 minutes, then cooled by a nitrogen flow to 100°C in one minute, and then to room temperature over twenty minutes. The heat treatment may vary, as discussed above. For example, for a biliary stent the maximum temperature is 450°C. For the prostate stent, the maximum temperature is 500°C for 30 minutes. Other materials include highly elastic stainless steel alloys such as those including molybdenum or cobalt.

As discussed, particular applications have preferred specifications and dimensions. These preferred dimensions are shown in TABLE 1. For example, a preferred esophageal stent is formed of wire whose diameter is 0.006"; the overall diameter *D* is 18mm with a flare 622 to 20 to 22mm at one end, and has 16 loops around its circumference. The flare is preferably 20mm in diameter and 1.5cm in length. A stent for the biliary duct is not flared at either end. A stent for the colon would be about 10 to 20mm in diameter and about 4 to 10 cm in length, and may have flared diameters at both ends.

Vascular stents are particular embodiments. The wall of a blood vessel stretches and contracts a small amount with each heartbeat but does not substantially extend radially inward. If the blood vessel is in an extremity, especially if it is near a joint, the length and bend of the blood vessel undergoes large changes. Vascular stents would be about 6mm in diameter. The radial force of the stent must be sufficient to maintain the lumen open and not inhibit blood flow. The wire diameter and composition would be selected to have high fatigue resistance, to compensate for the demands described above.

TABLE 1

	stent diam	stent length	wire diam	dim 1152	dim 1156	dim 1154	flared ends	flare diam	loops
esophagus	18mm	6-20cm	0.006"	0.120"	0.108"	0.062"	1	20-22mm	16
biliary duct	10mm	1-8cm	0.005"	0.114"	0.141"	0.040"	0	--	8
colon	10-30 pref 25mm	2-10cm pref 2-6cm	0.007"	3.1mm	2.6mm	1.2mm	2	30mm	24
prostatic urethra	10-20mm pref 14mm	2-6 cm	0.006"	3.2mm	2.4mm	1.3mm	0	--	16
coronary artery	2-5mm pref 2.7	1.5-3.5cm	0.002"-0.003"	1.8mm	1.1mm	0.65mm	0	--	6
trachea	14mm	2-6cm	0.006"	2.9mm	3.1mm	1.1mm	0	--	12

Other embodiments are within the following claims.
What is claimed is:

1. A method for providing reinforcement to a selected region of a selected body lumen that is subject to characteristic peristaltic motion in which a localized contraction of the lumen progresses in a wave-like manner down the lumen, said lumen, because of said peristaltic motion, characteristically exhibiting transient localized lengthening of the lumen wall in an amount that conforms to the profile of the peristaltic contraction wave, the method comprising the steps of:

selecting for use in said lumen a tubular structural stent formed by knitting a filament into interknit loops, the pattern of said loops selected such that from a relaxed state of said loops, each row of said loops may shift in the axial direction of the stent relative to and independently of the rows of knit loops on either side, said shifting by an amount sufficient whereby said characteristic local lengthening of the lumen wall over the length of the portion of said lumen that corresponds to the axial extent of said wave profile is accommodated by localized lengthening of the stent without disturbing the position of rows of loops that engage at-rest portions of the lumen wall distal of and proximal to said wave profile, said shifting accommodated by elastic bending of said filament, wherein the distance between successive rows of said loops elongates by a factor (ϵ), being the ratio between the maximum extended length l of said portion of said lumen during contraction and the wall length s of said portion of said lumen when at rest, i.e.

$$\epsilon = l/s;$$

delivering said selected stent into said body lumen; and

positioning said stent in contact with said wall at said selected region in said body lumen;

whereby said stent can locally lengthen and shorten with the physiologic motions of said body lumen during

peristalsis and thereby resist migration from said selected region.

2. The method of claim 1 further comprising:

selecting a stent in which said elongation factor ϵ of said stent is related to the maximum angle (θ) at which wall portions of said body lumen incline inward during the passage of said peristaltic contraction by the relationship:

$$\epsilon = 1 / \cos \theta.$$

3. The method of claim 2 in which the stent is selected to accommodate a maximum radial displacement amount (c) by which said wall is displaced into said lumen of about one half the diameter of said lumen.

4. The method of any one of the above claims 1-3 wherein said stent is knitted of metal wire to be self-expandable such that said stent expands outward against the body lumen wall by an elastic restoring force of the wire.

5. The method of claim 4 comprising treating the esophagus by insertion of the selected stent into the esophagus.

6. The method of claim 5 wherein said stent is selected on the basis of the lumen having a maximum angle θ of about 45° and an elongation factor ϵ of about 1.4.

7. The method of claim 6 comprising treating the esophagus with a knitted stent knitted from nitinol wire.

8. The method of claim 6 comprising treating the esophagus with a knitted stent knitted from nitinol wire having a diameter of about 0.15 mm.

9. The method of claim 4 comprising treating the esophagus with a knitted stent having a rest diameter of about 14 to 25 mm and a rest length of about 5 to 15 cm.

10. The method of claim 4 comprising treating the biliary duct, said selected knitted stent having a rest diameter of about 8 to 10 mm and a rest length of about 4 to 8 cm.

11. The method of claim 4 comprising treating the ureter, said selected knitted stent having a rest diameter of about 6 to 10 mm and a rest length of about 2 to 10 cm.

12. The method of claim 4 comprising treating the prostatic urethra, said knitted stent having a rest diameter of about 10 to 20 mm and a rest length of about 2 to 6 cm.

13. The method of claim 4 comprising treating the urethra, said knitted stent having a rest diameter of about 8 to 12 mm and a rest length of about 2 to 6 cm.

14. The method of claim 4 comprising treating the colon, said knitted stent having a rest diameter of about 10 to 20 mm and a rest length of about 4 to 10 cm.

15. The method of claim 4 comprising treating venous stenoses, said knitted stent having a rest diameter of about 12 to 25 mm and a rest length of about 4 to 10 cm.

16. The method of claim 4 comprising treating a body by hemodialysis by providing a hemodialysis shunt, said shunt in the form of a knitted stent having a rest diameter of about 6 to 8 mm and a rest length of about 2 to 6 cm.

17. The method of claim 4 comprising treating a body by providing a porta cava shunt, said shunt in the form of a knitted stent having a rest diameter of about 8 to 14 mm and a rest length of about 4 to 8 cm.

18. The method of claim 4 comprising treating the bronchial/tracheal lumens, said knitted stent having a rest diameter of about 8 to 25 mm and a rest length of about 1 to 8 cm.

19. The method of claim 4 comprising treating the gastro-intestinal lumen, said knitted stent having a rest diameter of about 8 to 20 mm and a rest length of about 1 to 25 cm.

20. The method of claim 4 wherein the free state of said stent has a point of constricted cross-section.

21. The method of claim 20 wherein said constriction further comprises a valve.

22. A unitary stent for providing reinforcement to a selected region of a selected body lumen, comprising:

a resilient cylindrical supporting mesh inner layer;

a resilient cylindrical retaining mesh outer layer of inner diameter about equal to the outer diameter of said inner layer; and

a semi-permeable compliant membrane sandwiched between and secured in position by said supporting mesh inner layer and said retaining mesh outer layer.

23. The stent of claim 22 wherein said membrane is composed of expanded polytetrafluoroethylene.

24. The stent of claim 21 wherein said inner and outer layers are formed by knitting a filament into interknit

loops, the pattern of said loops selected such that from a relaxed state of said loops, each row of said loops may shift in the axial direction of the stent relative to and independently of the rows of knit loops on either side, said shifting accommodated by elastic bending of said filament, wherein the distance between successive rows of said loops elongates by a factor (ϵ), being the ratio between the maximum extended length l of a portion of said lumen during contraction and the wall length s of said portion of said lumen when at rest, i.e.

$$\epsilon = l/s$$

whereby said stent can locally lengthen and shorten with the physiologic motions of said body lumen during peristalsis and thereby resist migration from said selected region.

25. A method ~~for manufacturing~~ a system for delivering a resilient ~~tubular device~~ into a body by reducing said tubular device from a rest diameter to a substantially reduced diameter, the method comprising the steps of:

providing a confining block having a bore at least as large as said reduced diameter and a slot in a side of said confining block, said slot having an end at said bore;

pinching a flat line in said tubular device;

inserting the ~~pinched~~ portion of said tubular device into said confining block, the pinched line of said tubular device lying in said slot and a contiguous portion of said tubular device lying in said bore;

inserting a first mandrel into the portion of said tubular device lying inside said bore;

inserting a second mandrel into said bore but outside said tubular device;

revolving said mandrels relatively about each other to roll said tubular device on itself until said tubular

device is entirely rolled and has said reduced diameter within said bore; and

removing said tubular device from said bore while restraining said tubular device in its reduced diameter condition.

26. The method of claim 25 wherein said removing step comprises:

slowly pushing said tubular device from an end of said bore and restraining said tubular device as it emerges.

27. The method of claim 26 wherein said restraining comprises wrapping a wire around said tubular device.

28. The method of claim 25 wherein said slot is tangent to said bore of said confining block.

29. The method of claim 25 wherein said tubular device comprises a stent knit of an elastic filament.

30. The method of claim 29 wherein said first mandrel comprises an elongated delivery carrier for said stent.

31. A method of manufacturing a wire medical device, the method comprising:

providing an elastic metal wire;

forming said wire so it defines, generally, a tube that has a predetermined geometry and length,

said tube being formed by bending said wire in a substantially regular pattern that forms the walls of said tube over said length, and thereafter

shaping the tube to form a device having a different, desired geometry by applying a mechanical deforming force to said tube so it conforms to said desired geometry and, while maintaining said deforming force, heating and then

cooling said tube such that said tube retains said desired geometry when said mechanical deforming force is removed.

32. The method of claim 31 comprising:
mechanically deforming said tube by confining at least a portion of it within a cavity of a die having a smaller geometry than said tube.

33. The method of claim 31 comprising:
mechanically deforming said tube by stretching at least a portion of it over a mandrel having a larger diameter than said tube.

34. The method of claim 31 comprising:
mechanically deforming portions of said tube by confining said portions within the cavity of a die and mechanically deforming other portions of said tube by stretching said other portions over a mandrel.

35. The method of claim 31 comprising:
shaping said tube to form a stent having an end portion in the form of a flare of larger diameter than other portions of said stent.

36. The method of claim 31 comprising:
shaping said tube to form a stent that has an end portion in the form of a flare of enlarged diameter at each end of the stent and a reduced diameter portion therebetween.

37. The method of claim 36 comprising:
shaping by mechanically deforming each end portion of said tube by stretching each end portion over a mandrel having a larger diameter than said tube.

38. The method of claim 31 comprising:

mechanically deforming said tube over at least about 10% of its length.

39. The method of claim 31 comprising:

forming a valve device by shaping said tube so it includes a portion of substantially reduced diameter, and

providing to said reduced diameter portion a wall material that is substantially impermeable to body fluid,

said valve device being capable of impeding the flow of body fluid through said reduced diameter portion until the pressure of said body fluid is sufficient to elastically widen said portion and allow flow therethrough, said portion of said device relaxing to said reduced diameter when the pressure of said bodily fluid decreases thereafter.

40. A method of manufacturing a wire medical device, the method comprising:

providing an elastic metal wire;

forming said wire so it defines a medical device generally in the form of a tube that has a predetermined geometry and length,

said tube being formed by bending said wire in a substantially regular pattern to form the walls of said tube over said length, said pattern including portions in which the wire is in overlapping, pressure contact, and

heating said tube for a prescribed period in the manner that pressure between wire portions in overlapping contact, created during said bending, is substantially relieved to improve the capability of said device to adaptively respond to change in the configuration of surrounding tissue.

41. The method of any one of claims 31 or 40 wherein:

said tube is formed by knitting said wire.

42. The method of claim 41 wherein:
said wire is selected from the group consisting of a nickel-titanium alloy and molybdenum- or barium-containing highly elastic stainless steel.

43. The method of claim 41 wherein:
said tube is heated to about 400-500°C for about 20-30 minutes.

44. The method of claim 41 wherein:
said device is formed by knitting on a knitting machine of the type including a knitting head that guides knitting needles as they reciprocate to form a knit pattern, said knitting needles drawing said wire into contact with said knitting head during the course of forming said tube,
the improvement comprising:
forming said knitting head from a durable, low friction polymeric material.

45. The method of claim 44 wherein:
said polymeric material is formed of delrin or nylon.

46. The method of claim 44 wherein portions of said knitting needles in contact with said wire during knitting include a durable, low friction polymeric material.

47. A method of manufacturing a wire medical stent device, the method comprising:
providing an elastic metal wire;
forming said wire so it defines, generally, a tube that has a predetermined first geometry and length,

said tube being formed by knitting said wire in a substantially regular pattern that forms the walls of said tube over said length.

48. The method of claim 47, comprising:

said pattern including portions in which the wire is in developing pressure contact and thereafter heating said tube for a prescribed period in the manner to pressure between wire portions in overlapping contact, created during said bending, is substantially relieved to improve the capability of said device to adaptively response to change in the configuration of surrounding tissue.

49. The method of claim 47, comprising constructing said stent for use in the coronary artery.

50. A medical device formed according to the method of claim 46.

51. A medical device for use in a body lumen, comprising:

a tube formed by a flexible wire bent in a substantially regular pattern to form the walls of said tube over a desired length, said pattern being configured to allow relative motion of adjacent portions of wire when said tube is subject to the physiologic motions of a body lumen,

said tube that having a shape of a varying geometry along its length, said shape being selected to improve the function of said device in the lumen in which said device is to be used.

52. The device of claim 51 wherein said shape is selected to complement the inner wall of the lumen in which said device is to be used.

53. The device of claim 52 comprising:

a shape wherein said tube has a larger diameter for part of its length for contacting a portion of said lumen having a corresponding large diameter and a smaller diameter for the rest of its length for contacting a portion of the lumen having a corresponding to smaller diameter.

54. The device of claim 51 comprising:

a shape wherein said tube has a flare to larger diameter at an end and a smaller diameter portion adjacent said flared end, said smaller diameter portion selected to conform to the diameter of said lumen and said flare serving to anchor said device in said lumen.

55. The device of claim 54 wherein said flare extends to a diameter about 15-25% larger than said reduced diameter portion and has a length of about 15-25% of the length of said tube.

56. The device of claim 54 wherein said tube has a flare at both ends with said smaller diameter portion therebetween.

57. The device of claim 54 comprising a secondary flare formed by the wire at the end of said pattern.

58. The device of claim 51 wherein said pattern is a knit pattern.

59. A valve device for implantation into a lumen of an organ of a body, comprising:

a tube formed by a flexible wire bent in a regular pattern to form the walls of said tube over a desired length, said pattern being configured to allow relative

motion of adjacent portions of wire when said tube is subject to the physiologic motions of a body lumen,

a portion of the tube having a much reduced diameter, and being provided with a material that is substantially impermeable to body fluid,

said device being capable of impeding the flow of body fluid through said reduced diameter portion until the pressure of said body fluid is sufficient to elastically widen said portion and allow flow therethrough, said portion of said device relaxing to said reduced diameter when the pressure of said bodily fluid decreases thereafter.

60. A medical stent device for use in a body lumen, comprising:

a tube ~~formed by a~~ flexible wire knitted in a substantially ~~regular~~ pattern to form the walls of said tube over a ~~desired length~~, said pattern being configured to allow relative motion of adjacent portions of wire when said tube is subject to the physiologic motion of a body lumen,

a flare to larger diameter at an end extending over multiple knit row loops and a smaller diameter portion adjacent said flared end, said smaller diameter portion selected to conform to the diameter of said lumen and said flare ~~serving to~~ anchor said device in said lumen.

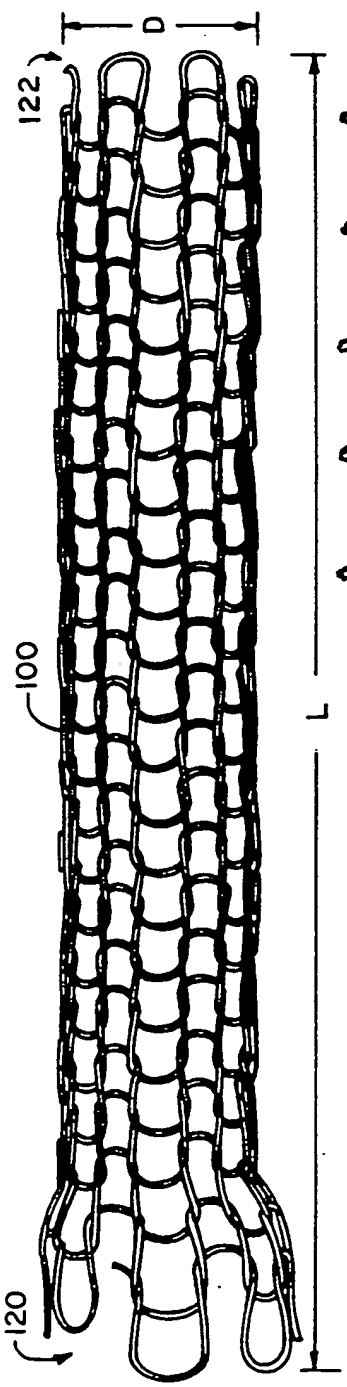


FIG. I

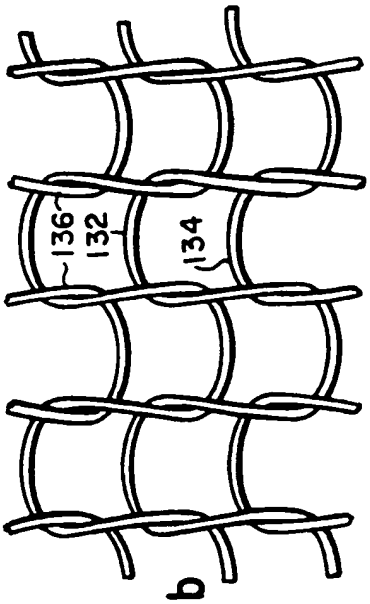


FIG. Ib

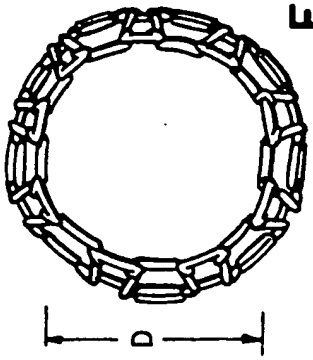


FIG. Ia

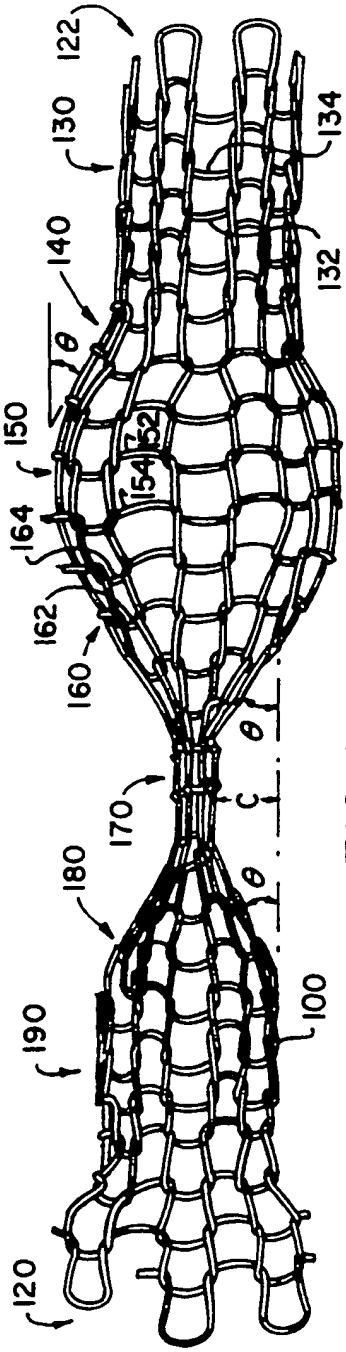


FIG. Ic

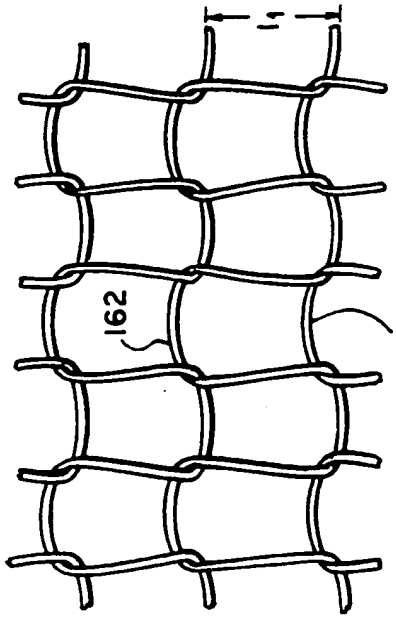


FIG. 1e

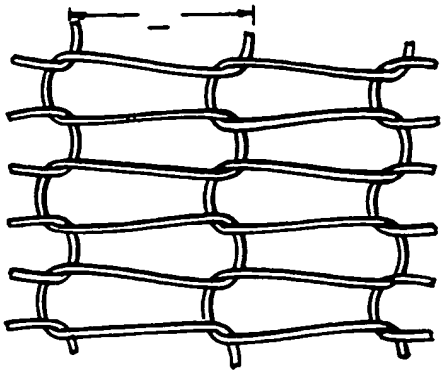


FIG. 1h

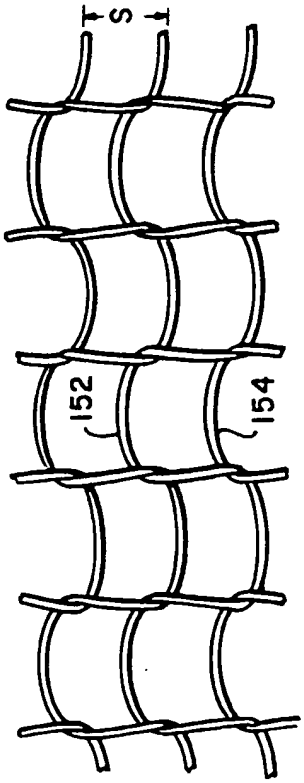


FIG. 1f

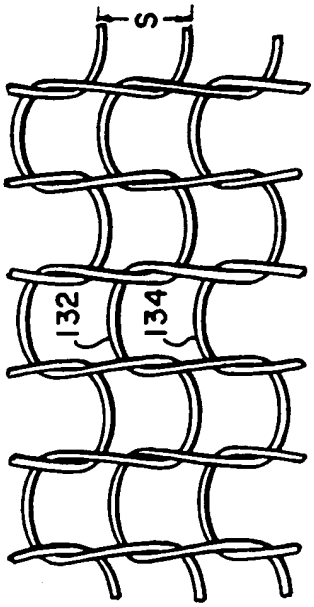


FIG. 1d

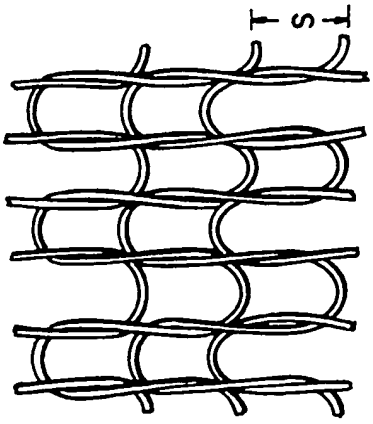


FIG. 1g

FIG. 2a

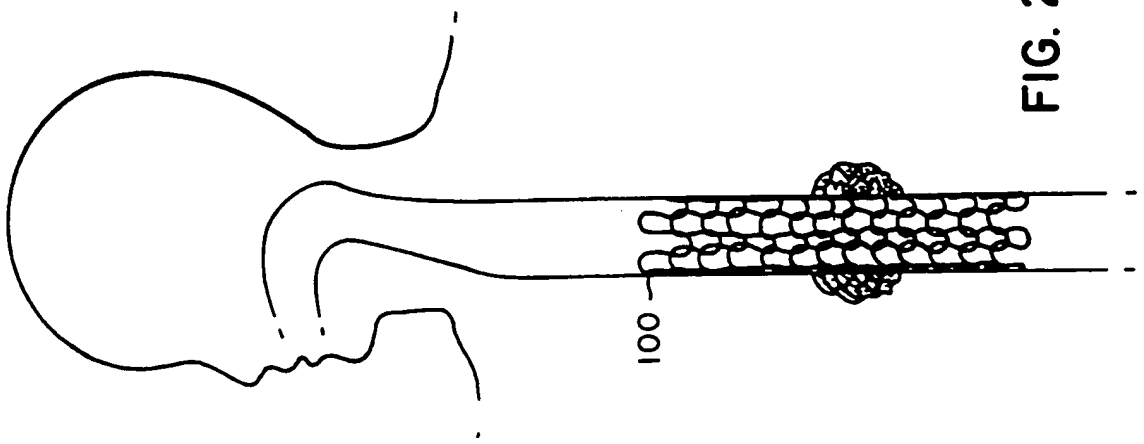
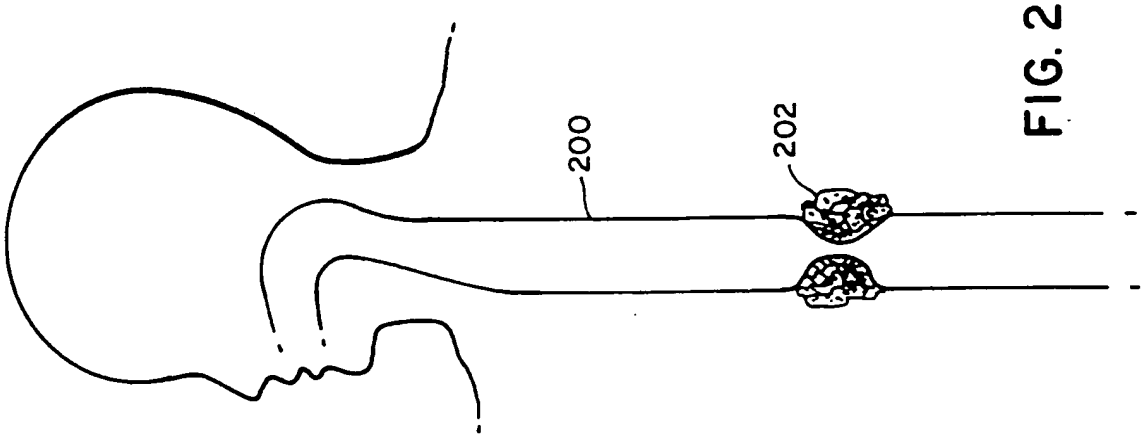


FIG. 2



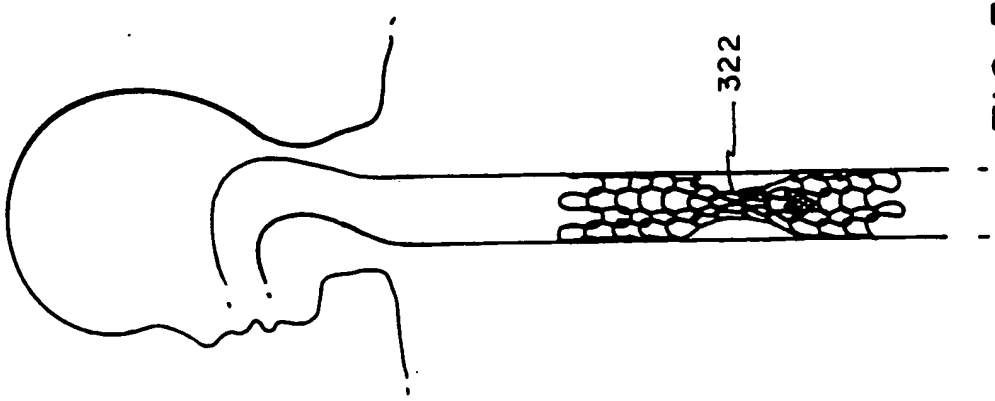


FIG. 3b

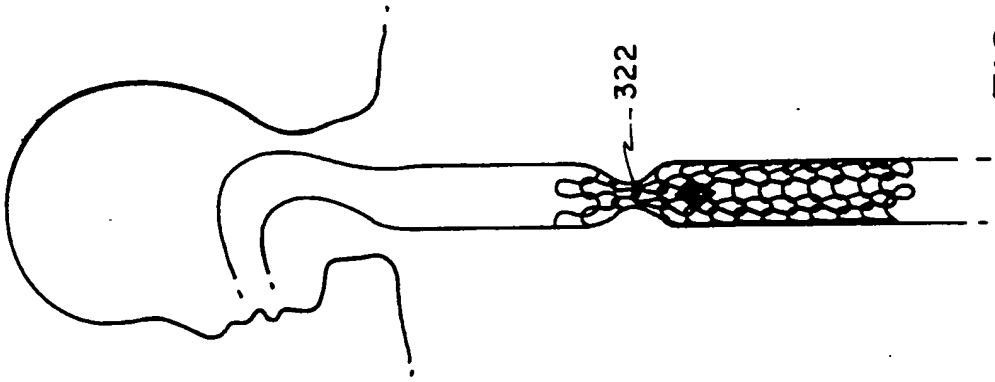


FIG. 3a

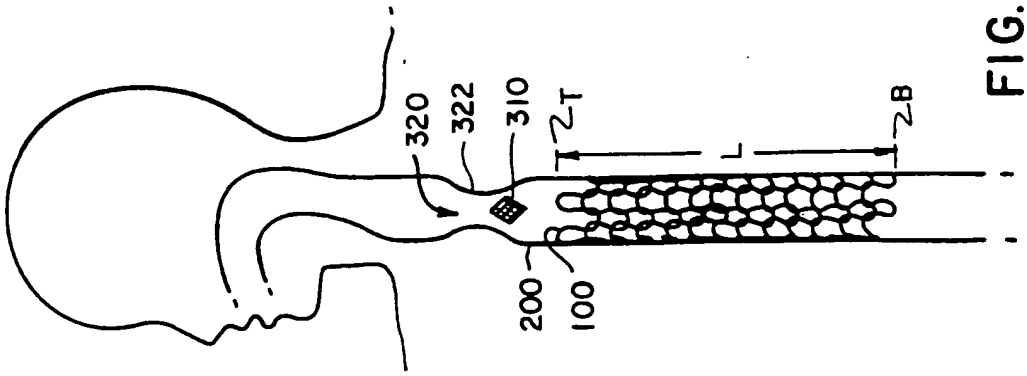


FIG. 3

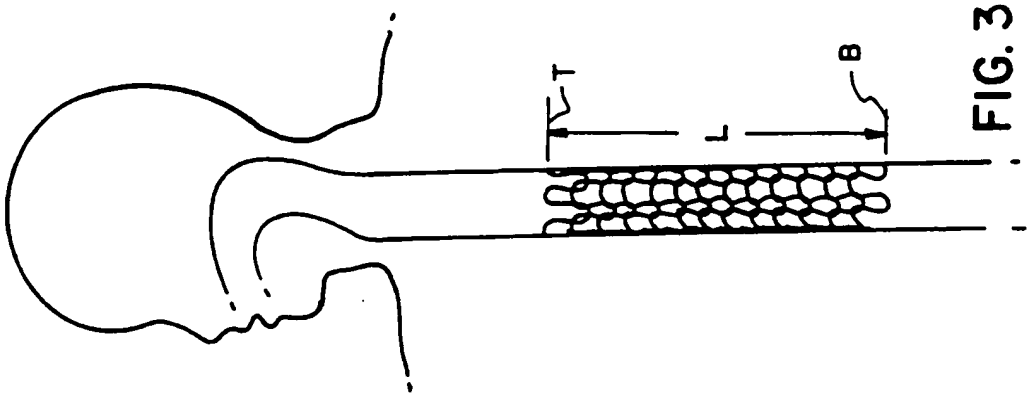


FIG. 3e

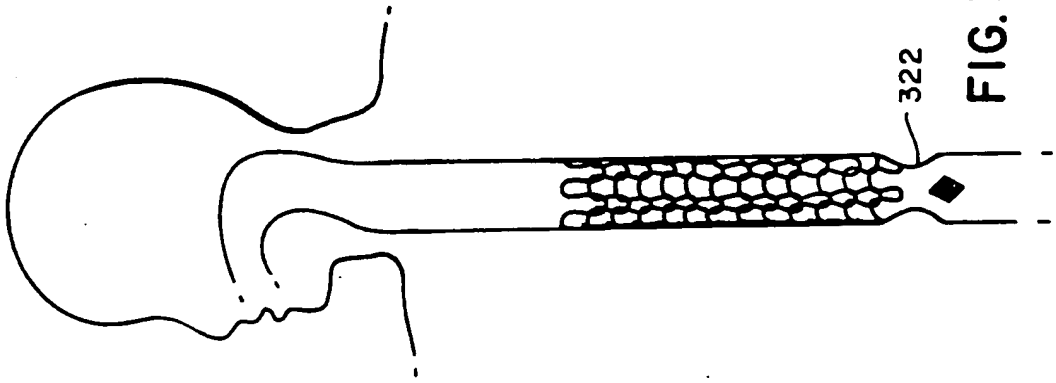


FIG. 3d

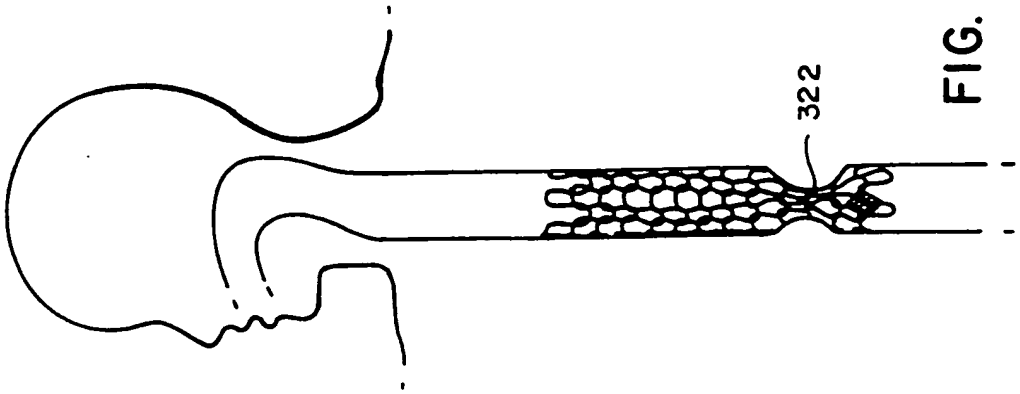


FIG. 3c

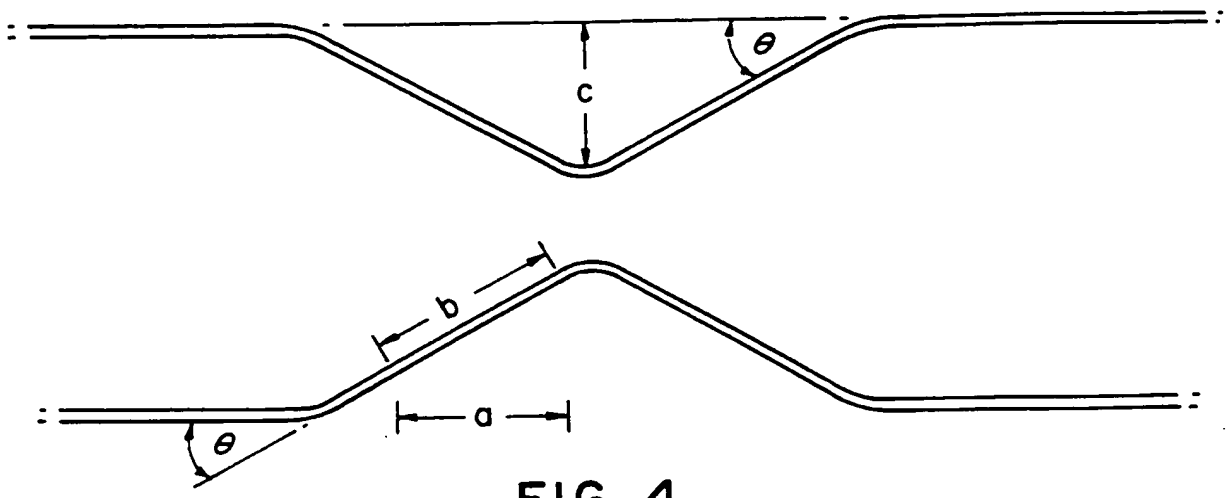


FIG. 4

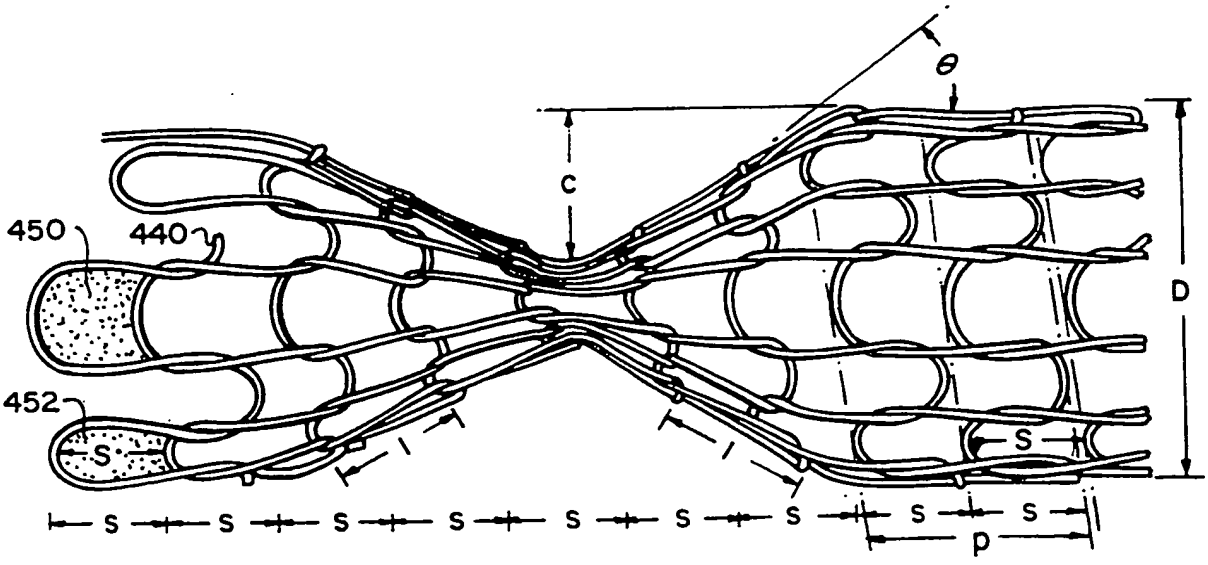


FIG. 4a

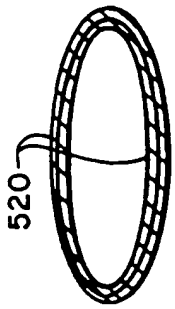


FIG. 5b

FIG. 5a

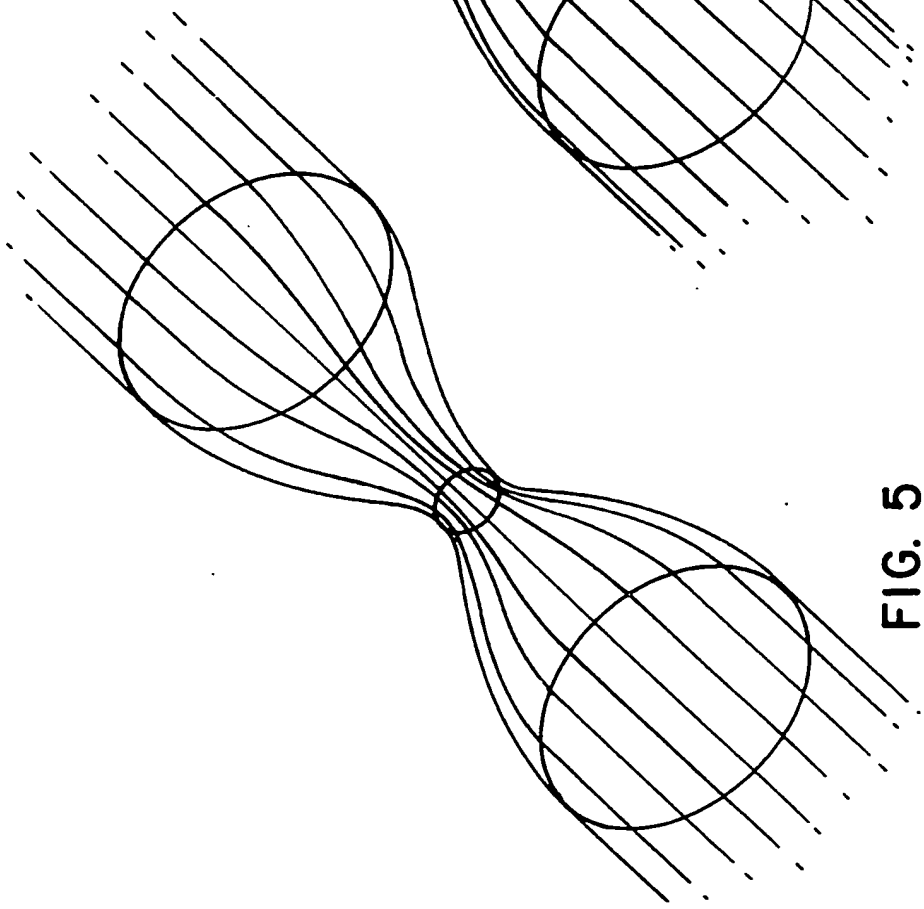


FIG. 5

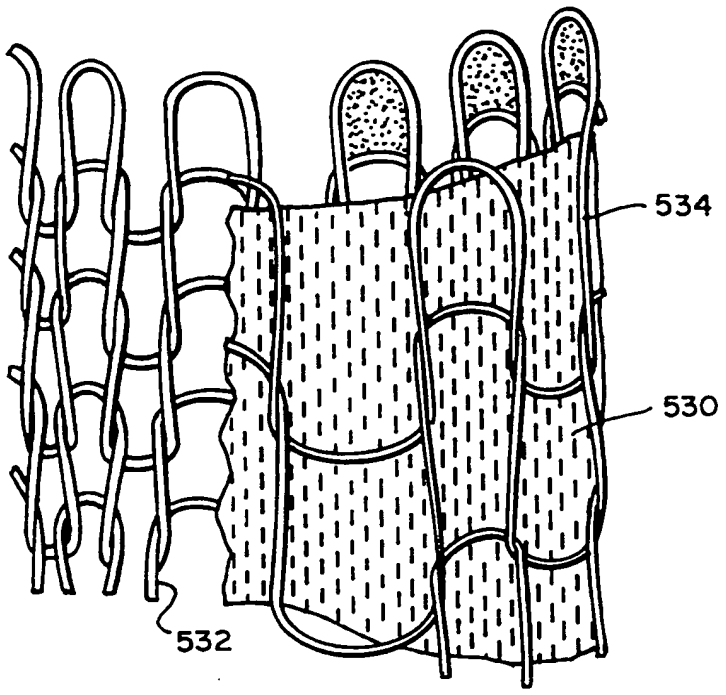


FIG. 5c

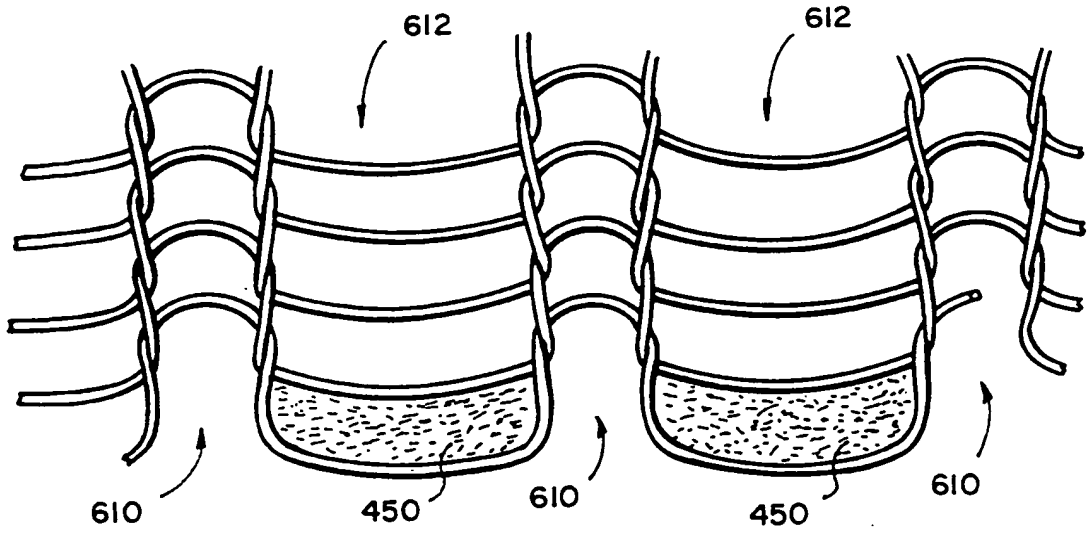


FIG. 6

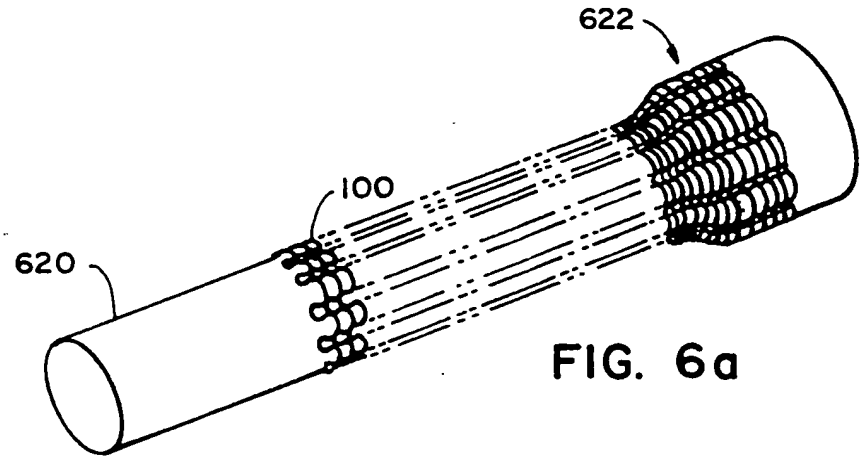


FIG. 6a

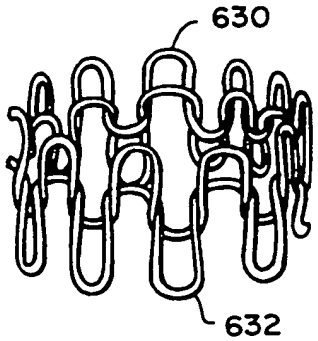


FIG. 6b

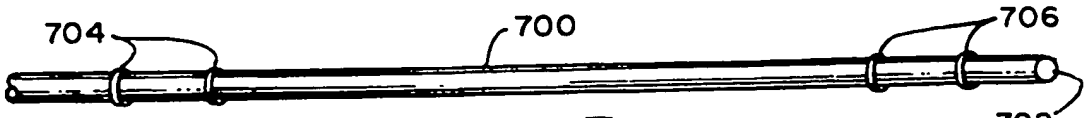


FIG. 7

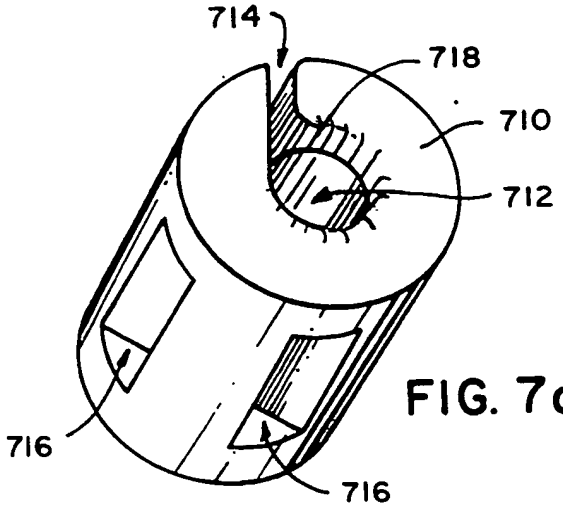


FIG. 7a

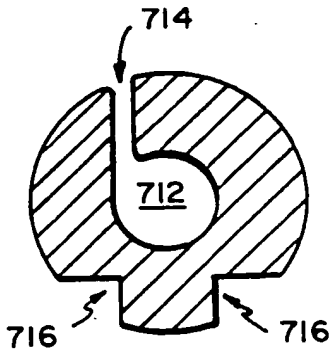


FIG. 7b

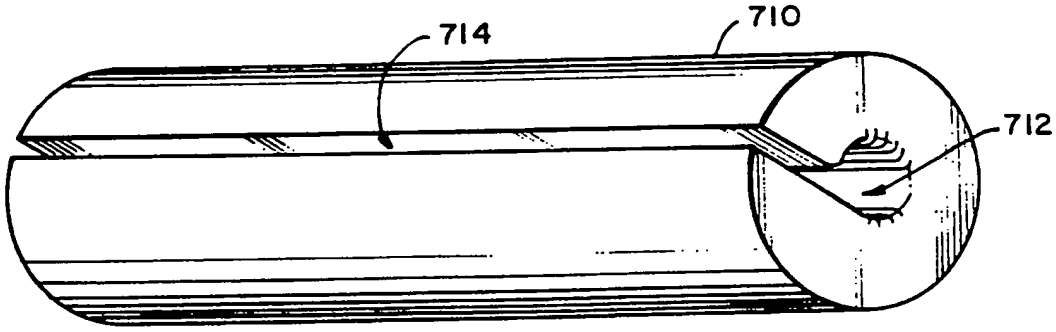


FIG. 7c

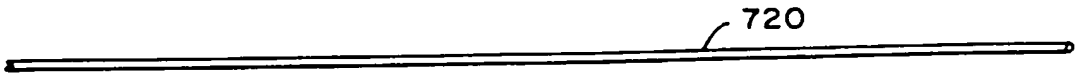


FIG. 7d

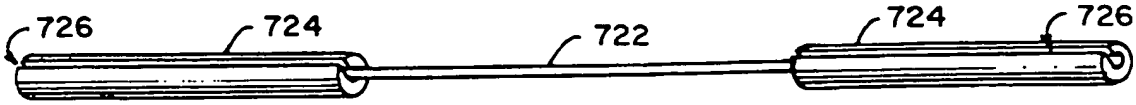


FIG. 7e

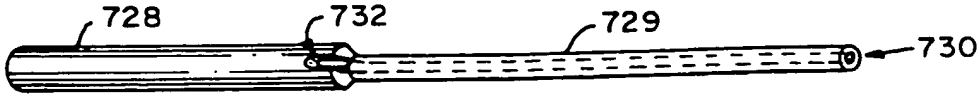


FIG. 7f

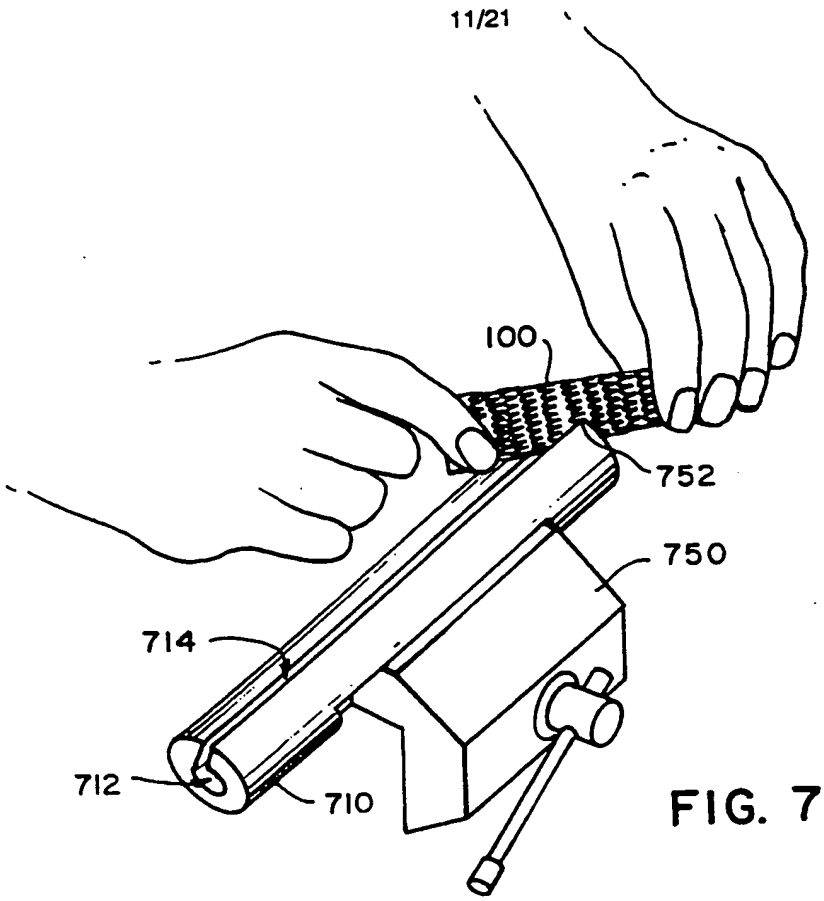


FIG. 7g

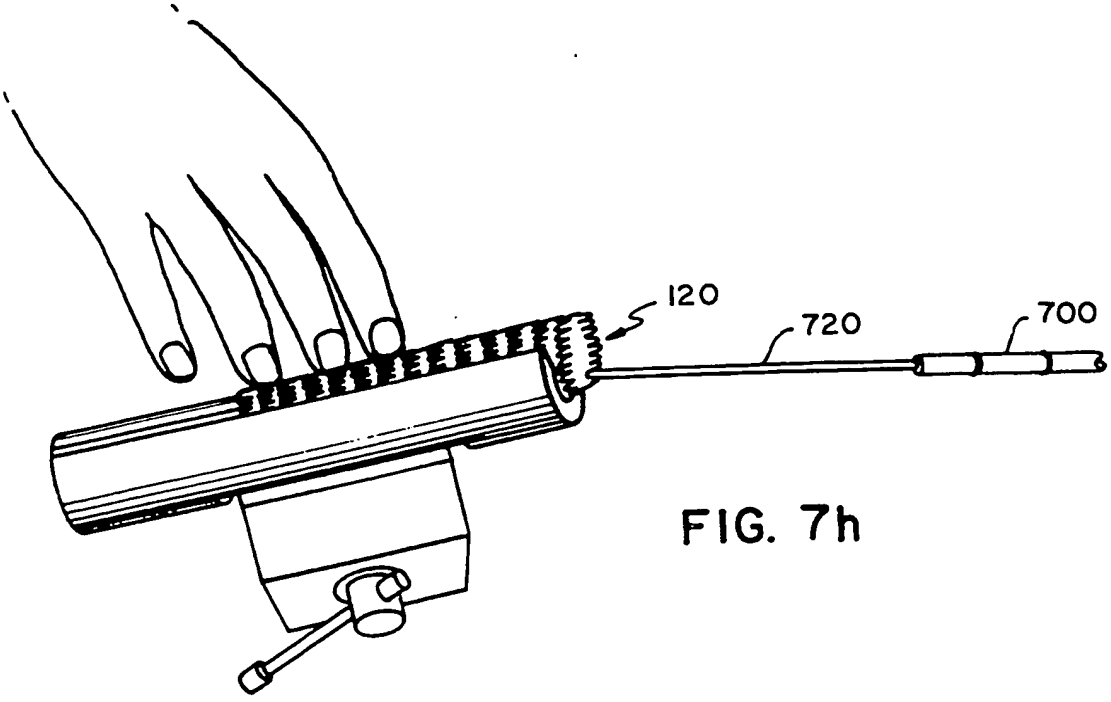


FIG. 7h

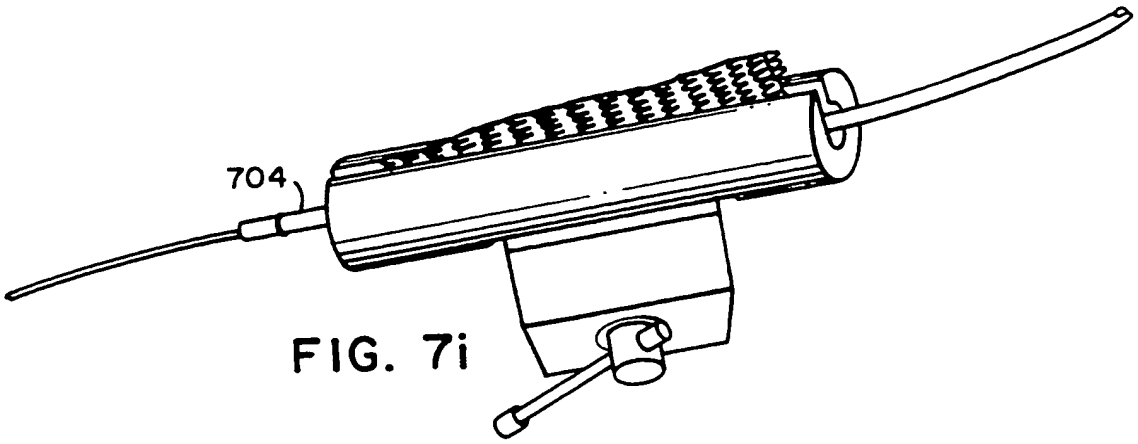


FIG. 7i

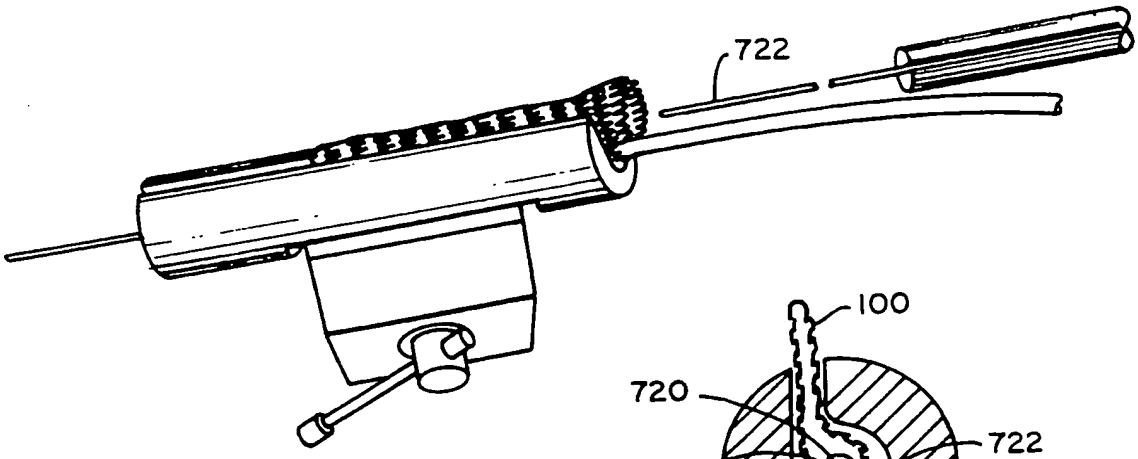


FIG. 7j

FIG. 7k

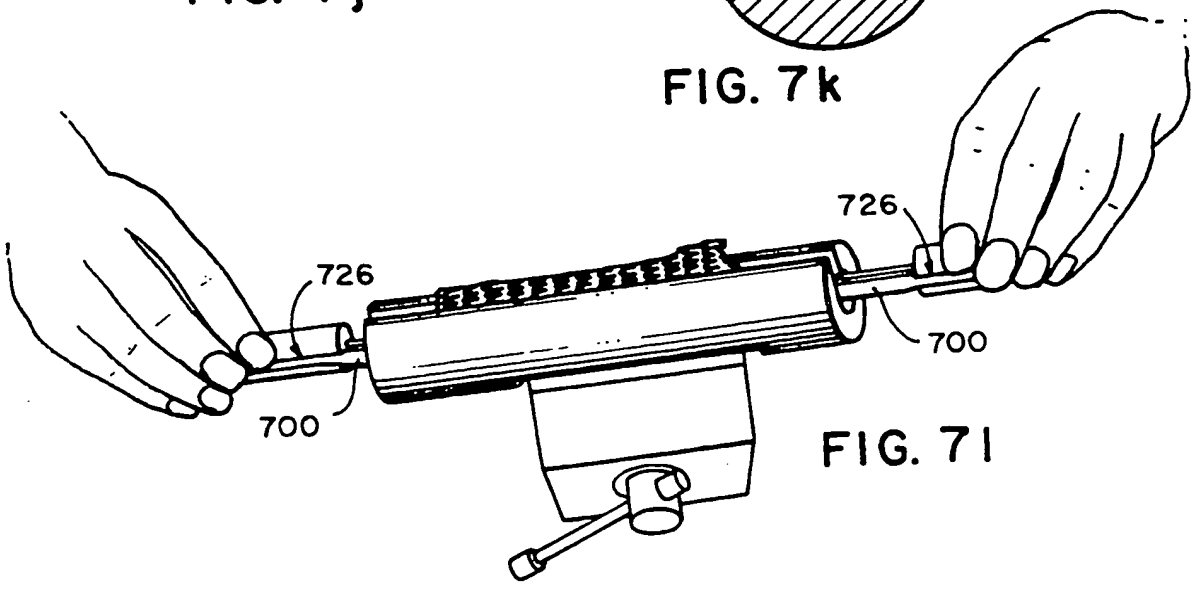


FIG. 7l

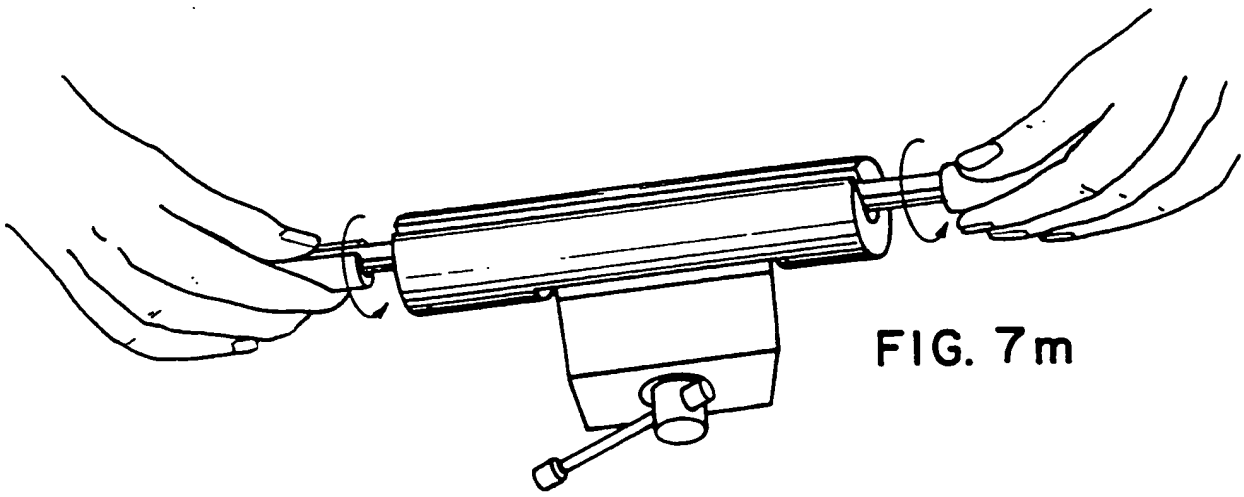


FIG. 7m

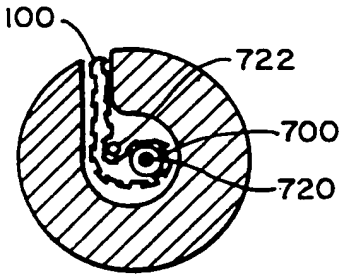


FIG. 7n

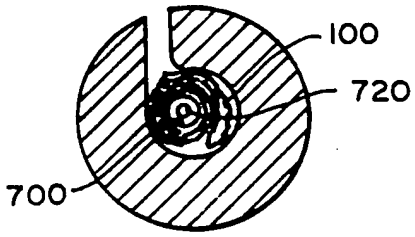


FIG. 7o

FIG. 7p

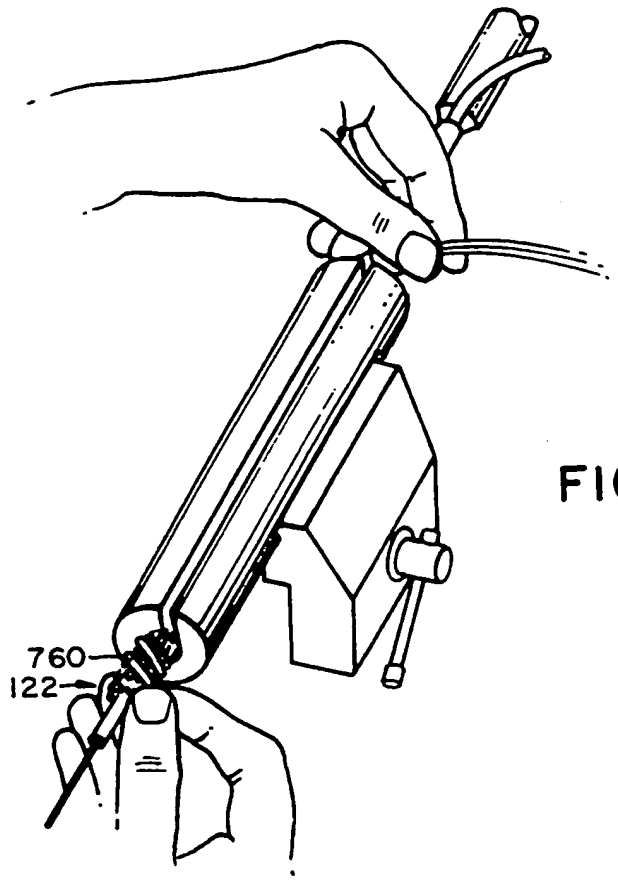


FIG. 7q

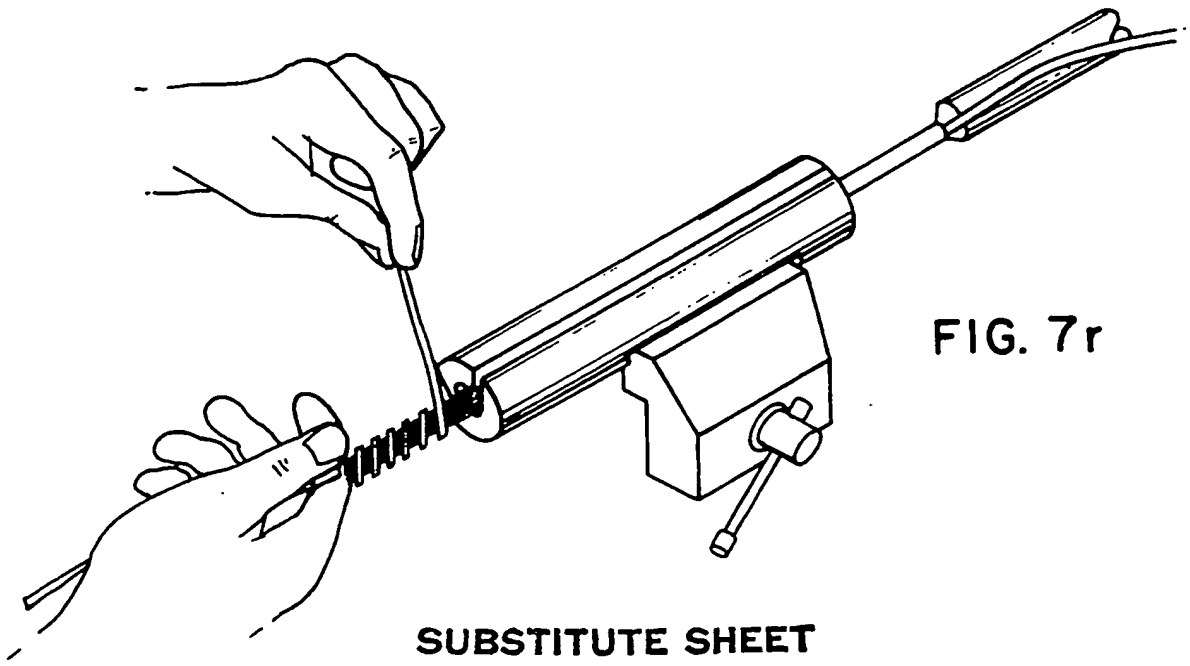
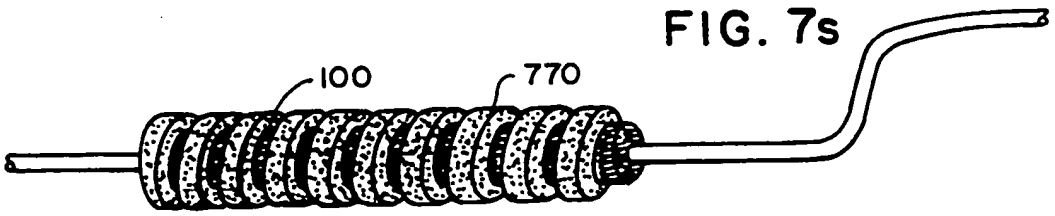


FIG. 7r

FIG. 7s



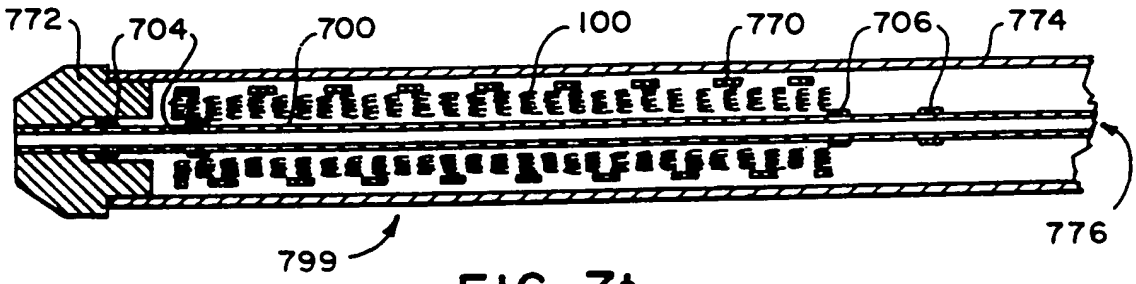


FIG. 7t

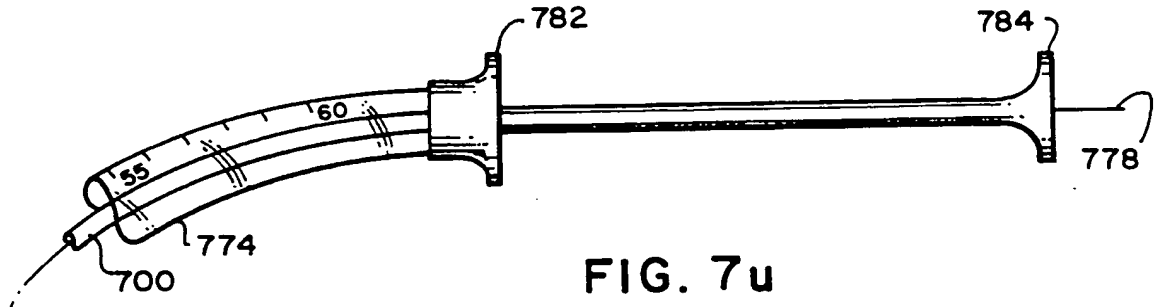
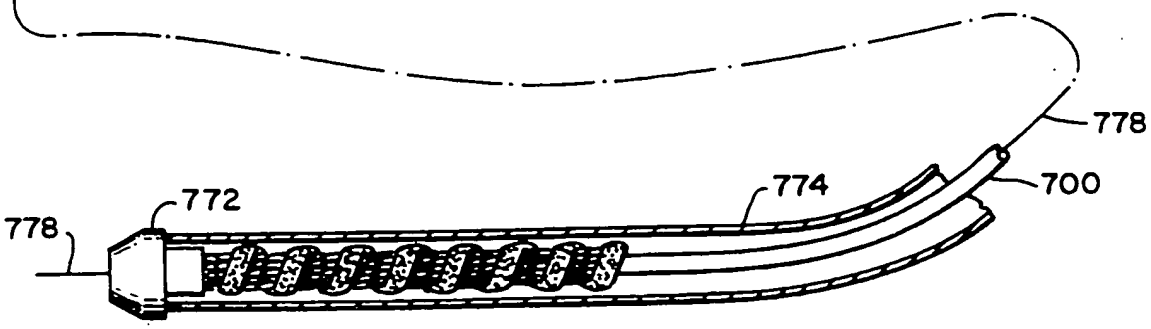


FIG. 7u



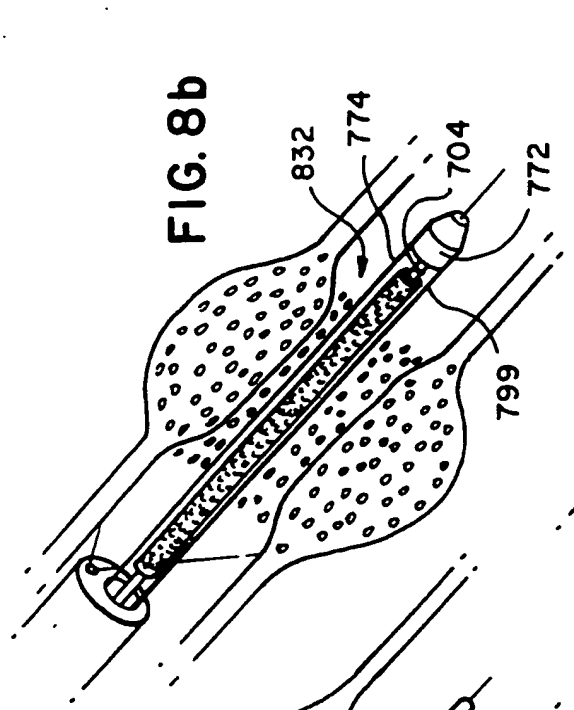


FIG. 8b

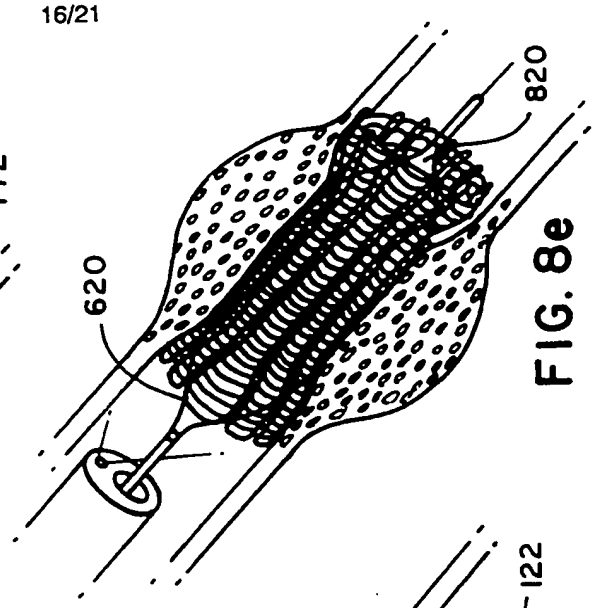


FIG. 8e

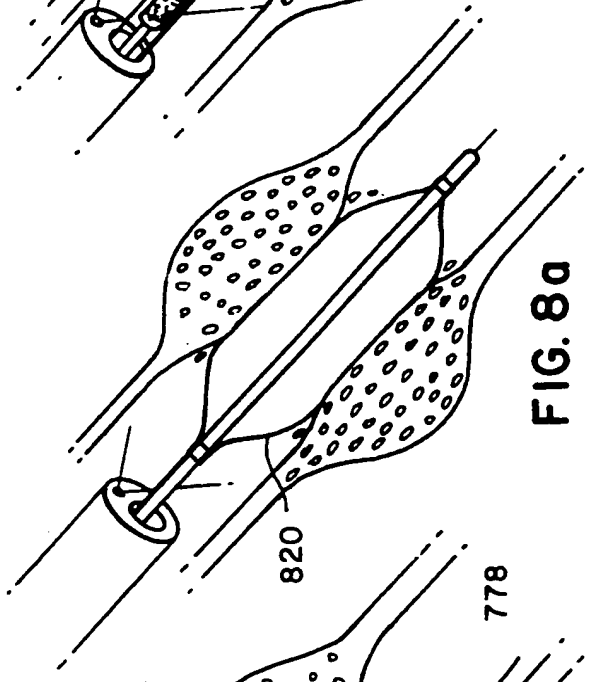


FIG. 8a

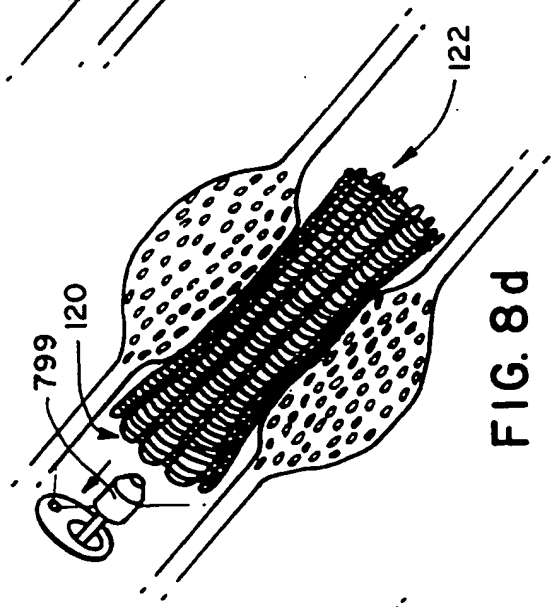


FIG. 8d

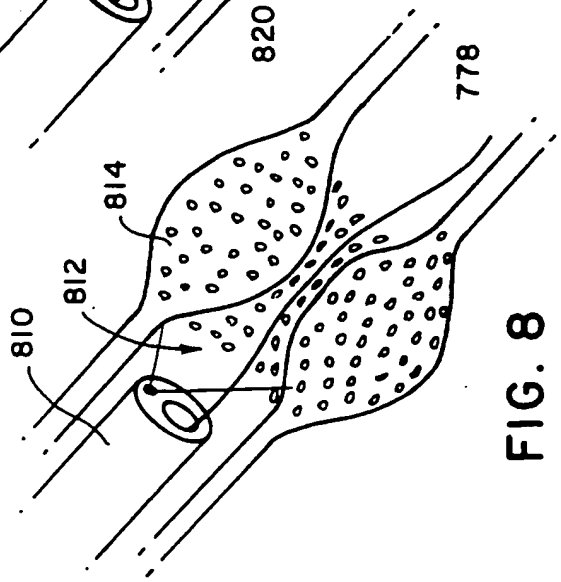


FIG. 8

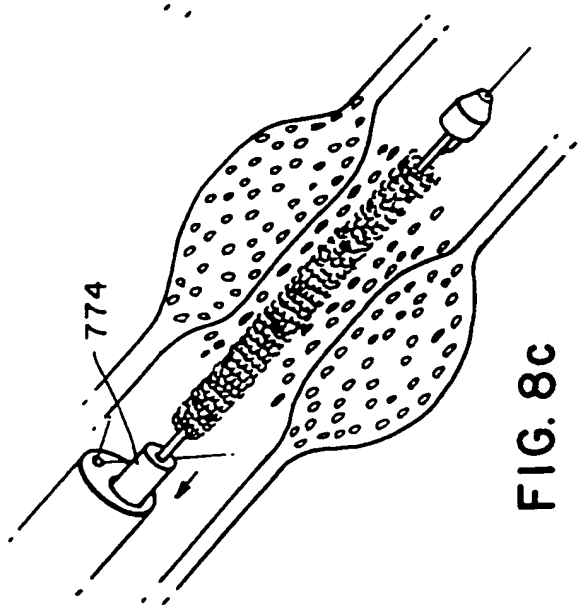


FIG. 8c

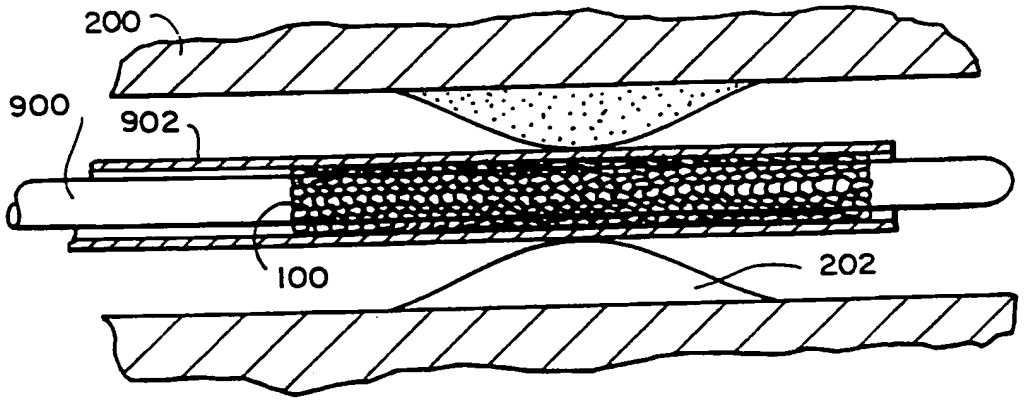


FIG. 9

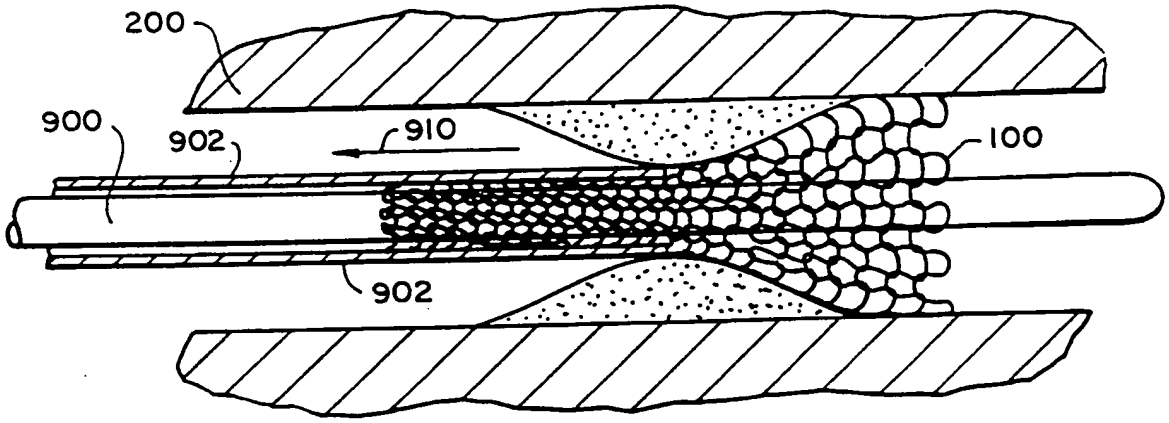


FIG. 9a

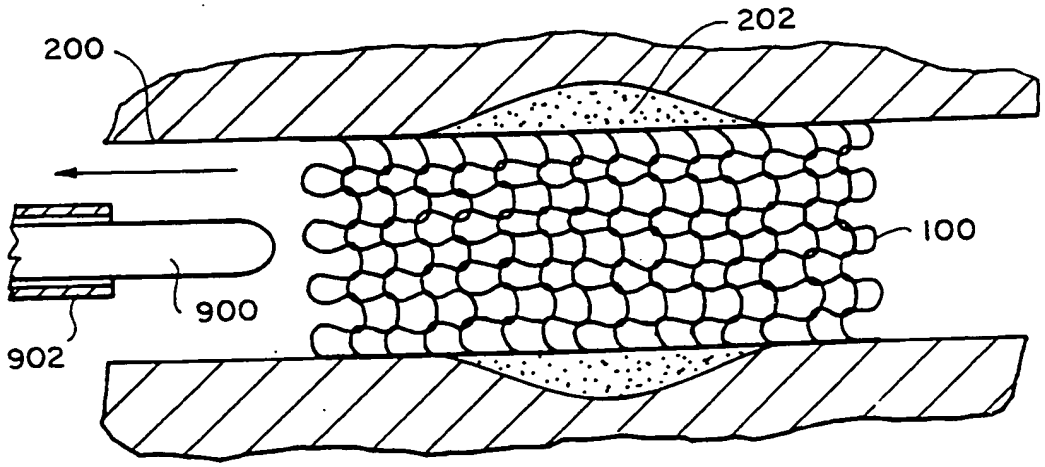


FIG. 9b

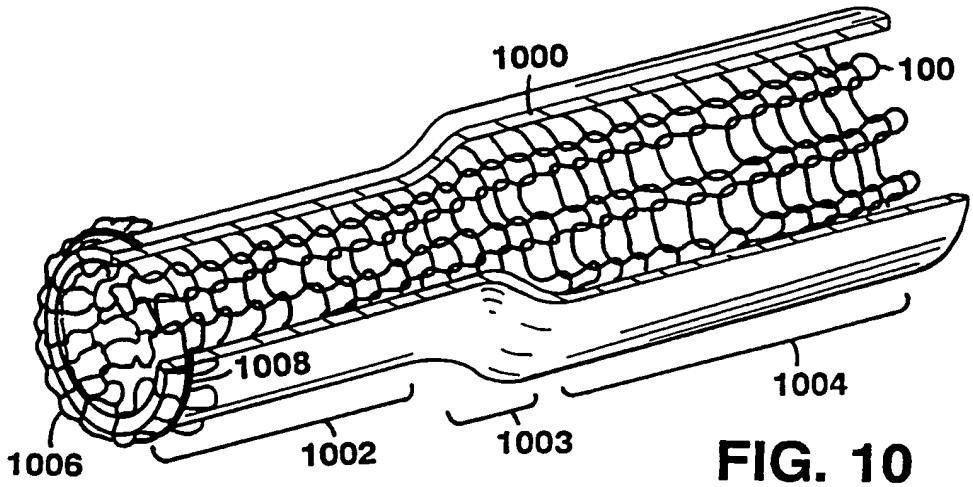


FIG. 10

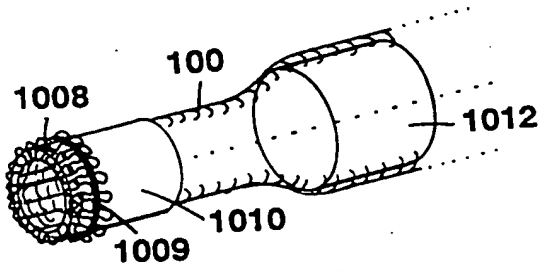


FIG. 10a

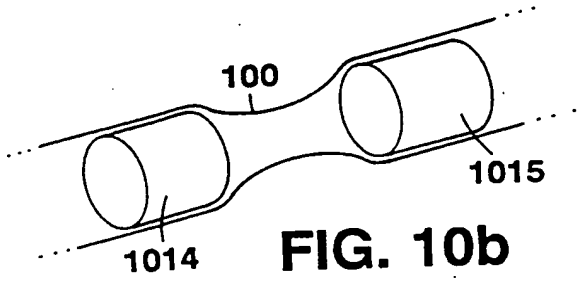


FIG. 10b

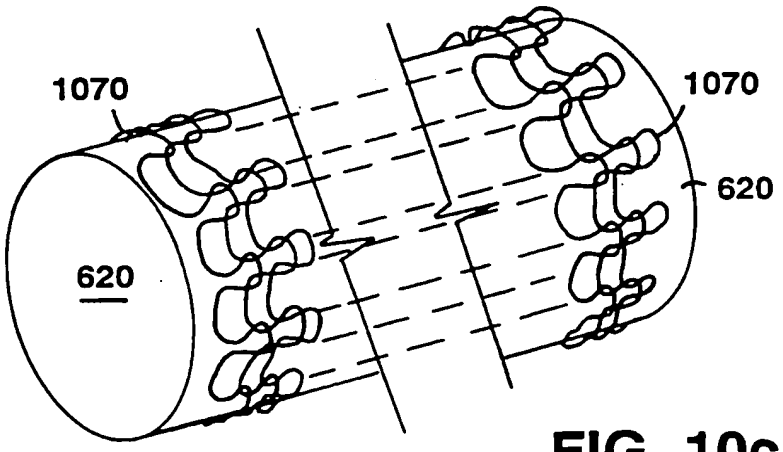


FIG. 10c

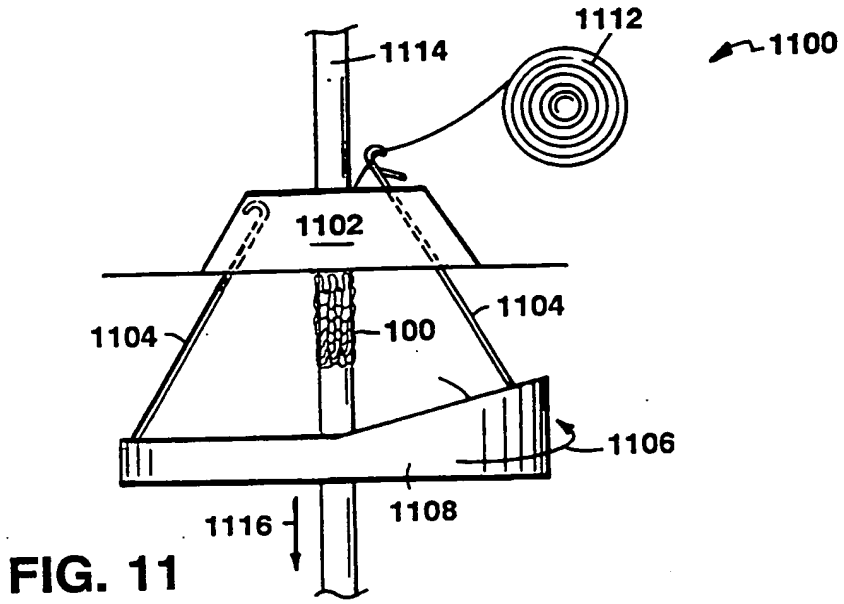


FIG. 11

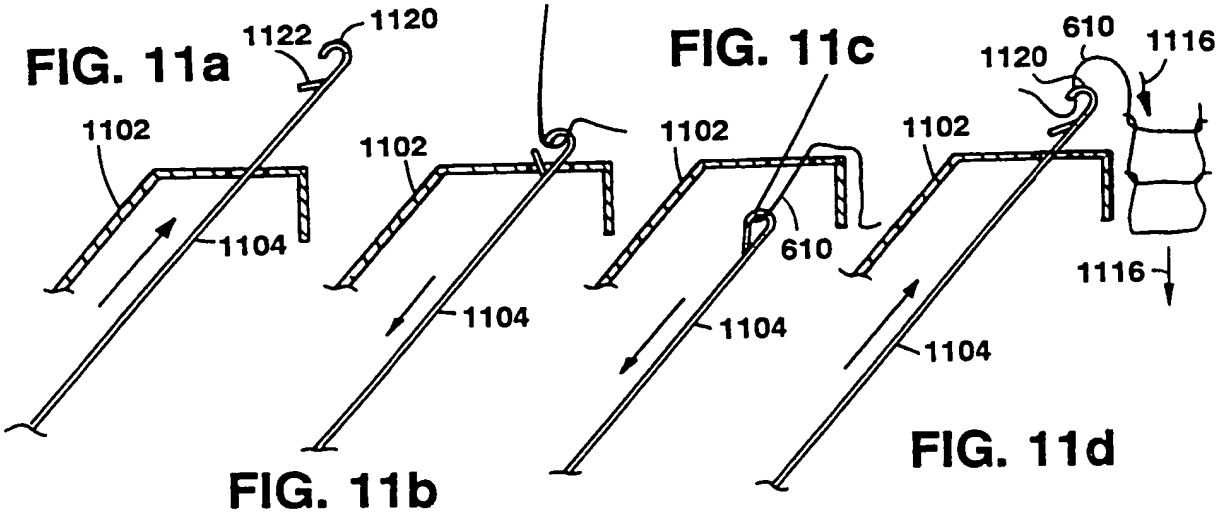


FIG. 11a

FIG. 11b

FIG. 11c

FIG. 11d

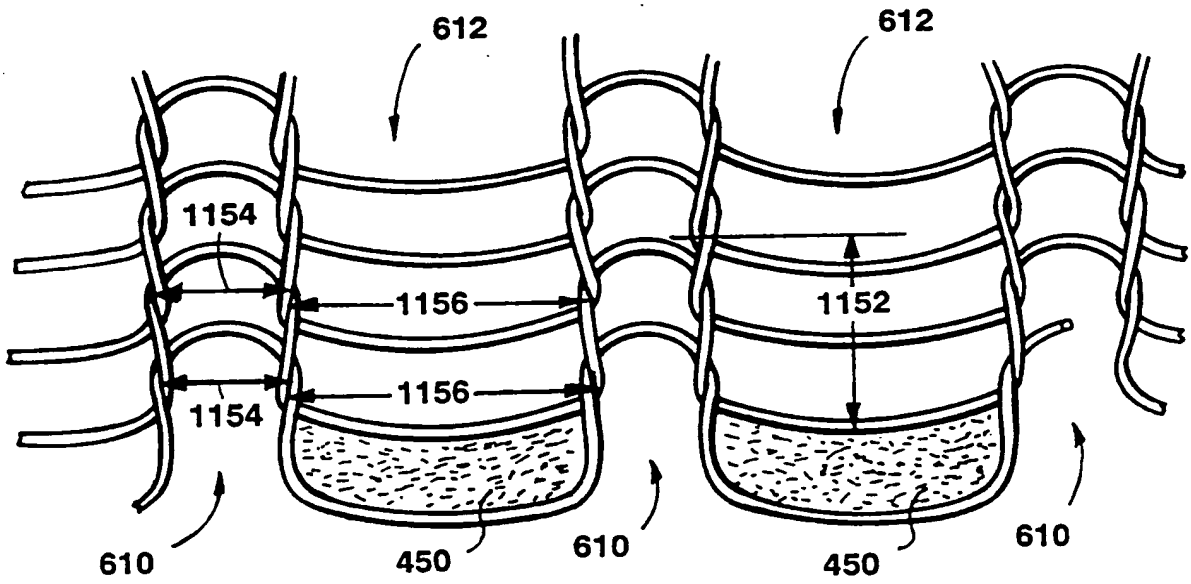
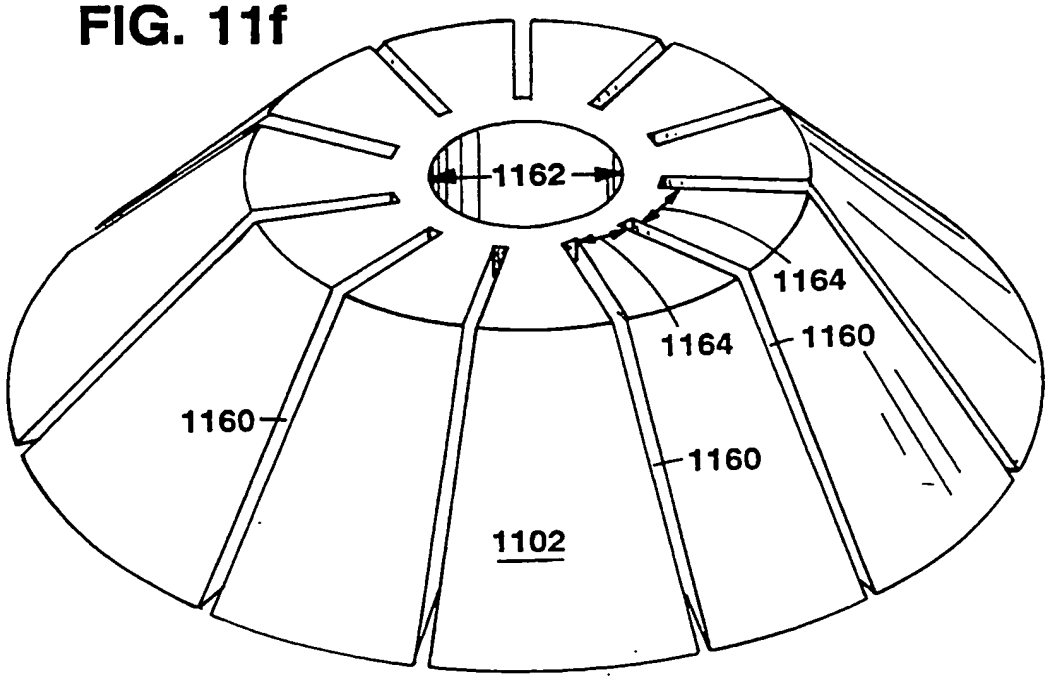


FIG. 11e

FIG. 11f



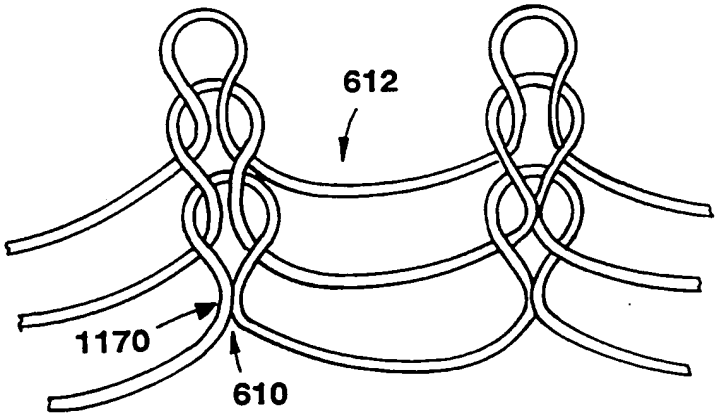


FIG. 11g

INTERNATIONAL SEARCH REPORT

Int. ational application No.
PCT/US93/09717

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61F 21/06; A61M 29/00
US CL :623/1, 12; 606/194
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1, 11, 12; 606/191-200; 600/36

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,950,227 (Savin et al.) 21 August 1990. See column 5, line 40 - column 6, line 39.	31, 38-42, 47-54, 58-60 --- 55
Y	WO, A, 8,402,266 (Possis et al.) 21 June 1984.	36, 56, 57
A	WO, A, 8,201,647 (Kaster) 27 May 1982.	1-60
A	DT, A, 2,461,370 (Savage et al.) 03 July 1975.	1-60
A	WO, A, 8,303,752 (Wallsten) 10 November 1983.	1-60

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be part of particular relevance
"E" earlier document published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 JANUARY 1994	14 APR 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer FOR Debra Brittingham Telephone No. (703) 308-3060

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